

# **EXHIBIT B**

# **John Wagner**

## **General Reliance List *in Addition to Materials Referenced in Report***

### **MDL Wave 6**

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Yonguc, T. Effectiveness of Transobturator Tape Procedure in Obese and Severely Obese Women: 3-Year Follow-Up. <i>Urology</i> 2015; 86: 244-249
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Zyczynski, Goldman, Sirls (UITN) - Change in overactive bladder symptoms after surgery for SUI in women. <i>Obstet Gynecol</i> 2015;126:423-30

**Production Materials**

<b>Document Description [Bates Range]</b>
"State of the knowledge" in "mesh shrinkage" (Adkins Trial Exhibit P1235)
"Things to Consider" (Adkins Trial Exhibit P1676)
(09.06.2006) - Peter Meier LIGHTning Presentation.
[000061-63] Version A - TVT Secur Harms/Hazards Table
2003 (14 Day Rabbit Study) PSE 02-0579 Stamped Copy March 10, 2003 R&D - Central File: ETH-11280; ETH-11285-297; ETH-11312-315
2006 Mar 3 Flatow memo - CPC-2006-0165 Performance evaluation of TVT PROLENE blue Mesh_ Elongation Properties of Mechanical Cut verses Laser Cut
2011 Native Pelvic Organ Prolapse Patient Counseling Guide
2013 Hinoul Clinical Evaluatiown Report - Gynecare TVT™ Family of Products
91 Day Tissue Reaction Study
A Solution-Gynecare TVT Tension-Free Support for Incontinence.
April 17, 2007 email -- maybe powerpoint of K. Spychaj shown here - not sure (Adkins Trial Exhibit P0863)
Aran Maree CV (T-890) (Adkins Trial Exhibits DX24678)
Athos/Aramis/Porthos, Concept - Feasibility , June 27, 2003
Axel Arnaud CV (Adkins Trial Exhibit DX10124 (T-834)
Axel Arnaud, M.D. Powerpoint presentation titled Graft or No Graft
Bacterial Analysis of Explanted Transvaginal Meshes
Biocompatibility of Meshes
Chronology - D-9
Clinical Evaluation Report - Gynecare Prolift signed by P. Hinoul on 04.26.2013
Comparison of pore sizes (this is when Ultrapro was first introduced) (Adkins Trial Exhibit P0705)
Correspondence between Morgan Liscinsky of FDA & Bloomberg re: Johnson & Johnson Vaginal Mesh Implant.
Curriculum Vitae of Axel Arnaud, M.D. (Adkins Trial Exhibits DX10124)
Depo Ex. 6 to the Deposition of Aran Maree taken on 07.23.13 - Presentation: TVT-Secur Australian Experience - Discussion with TGA. Canberra, 9 January 2008. (Adkins Trial Exhibits DX24547R)
Depo Exhibit No.19 to the 02.22.2017 Deposition of Bruce Rosenzweig, M.D. - Picture of Ruler with Handwritten Notations (Adkins Trial Exhibits DX10084)
DEPO.ETH.MESH.00000367-68 - T-2265 (Prolene Explants - IR Microscopy)
DEPO.ETH.MESH.00004755 - Guidoin Explant
DEPO.ETH.MESH.00004755 - Report: Quebec Explants. 1.20.88
Document re: porosity of Gynemesh PS
DX23600-R.1-3 - Prolene Resin Manufacturing Specifications 1.23.03
Email from Aran Maree, MD, Medical Director Australia/New Zealand sent email dated 10.25.07 re TVT-S in Australia (Adkins Trial Exhibit P0429)
Email from Joerg Holste, then to document referenced therein called "Shrinking Mesh" (Adkins Trial Exhibit P1846)
Email string re - Revised write up of the DeLeval and Waltregny visit
ETH MESH 05795421-508 - Gynecare TVT Tension-Free Support for Incontinence: Professional Education Slides.
ETH MESH 08476210-6342 - TVT 510(k)
ETH.MESH.00001595-606 - Reisenauer, C., et al. Anatomical conditions for pelvic floor reconstruction with polypropylene implant and its application for the treatment of vaginal prolapse. Eur J Obstet Gynecol (2006).

**Production Materials**

ETH.MESH.00004781-786 - Prolift +M: Biocompatibility is the science of living better.
ETH.MESH.00006636 - Interim report mesh explants pelvic floor repair
ETH.MESH.00006796 - Presentation-Stand and Deliver-Pelvic Floor Repair
ETH.MESH.00012009-089 - Clinical Study Report: Clinical assessment of feasibility, complications and effectiveness at twelve months, three years and five years of the TVM technique for genital prolapse.
ETH.MESH.00016032-039 - Kohli, N., et al. Augmenting pelvic floor repairs: new materials and techniques. OBG Management (2006) S1-S8.
ETH.MESH.00017362-368 - Elmer C, et al. Histological inflammatory response to transvaginal polypropylene mesh for pelvic reconstructive surgery, J Urol (2009), 181 (3), 1189-95.
ETH.MESH.00017553-560 - Tunuguntla, H. Female Sexual Dysfunction Following Vaginal Surgery: A Review. Journal of Urology 2006; 175: 439-446
ETH.MESH.00018382 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh in the Treatment of Pelvic Organ Prolapse
ETH.MESH.00028555-556 (Adkins trial exhibit P2669)
ETH.MESH.00030098 - Memo from Anthony Powell and Marianne Kaminski to Gynecare Continence Health Sales Team re GYNECARE TVT Physician Training Policy
ETH.MESH.00031538 - Presentation: Gynecare Professional Relations and Professional Education "Educating Customers Worldwide to improve the lives of women"
ETH.MESH.00034061-069 - Gynecare TVT SECUR* System: Key Technical Points
ETH.MESH.00034720-724 - Rezapour, M. A 3-month preclinical trial to assess the performance of a new TVT-like mesh (TVTx) in a sheep model. Inte Urogynecol J 2006
ETH.MESH.00071794 - Email re: TVT IFUs on tape extrusion, exposure and erosion
ETH.MESH.00074499 - Gynecare Prolift +M-Training Presentation
ETH.MESH.00082668-691 - August 23, 2005 Memo to Dan Smith RE: Final report, PSE Accession Number 05-0396, PROJECT Number 67379
ETH.MESH.00086463-464 - Email from P. Hinoul to Z. Viana, et al. re: Prosima take away messages.
ETH.MESH.00088927-939 - 2007 ACOG Practice Bulletin No. 85 re: Pelvic Organ Prolapse.
ETH.MESH.00126755-757 - Email string, top one from M. Yale to J. Paine, et al. re: Draft FDA response on Prolift+M for input
ETH.MESH.00128978-979 - Email from Jacqueline Russo-Jankewicz to Devon Prutzman December 2, 2007 RE: TVT-S Australia standby
ETH.MESH.00130934-41 - July 30, 1998 Meeting Notes re TVT
ETH.MESH.00130950 - ABS 004 An Evaluation of the Gynecare TVT Secur® System (tension-free support for incontinence) for the treatment of stress urinary incontinence.
ETH.MESH.00130950 - Karram, M. ABS 004 An Evaluation of the Gynecare TVT Secur* System (Tension-free support for incontinence) for the treatment of stress urinary incontinence.
ETH.MESH.00133502-504 - (11.23.2005) Email string, top one from Quentin Manley to multiple recipients re: Prolift improvements - Professor Eberhard (Frauenfeld, Switzerland).
ETH.MESH.00134794 - Email from Jason Hernandez to Nicholas Antoun February 27, 2009 RE: TVT WORLD Board meeting presentation; Powerpoint TVT WORLD Registry Maximizing the investment EWHU Board March 2, 2009
ETH.MESH.00134794-795 - Jason Hernandez email to Nicholas Antoun et al dated 02.27.2009 attaching TVT World Board meeting presentation (Engleman Trial Exhibit P0086)(Adkins Trial Exhibit P0086)
ETH.MESH.00143177-185 - Lucente, V. ABS 49 TVT Secur Sugical Technique and Learning Tips and Tricks.

**Production Materials**

ETH.MESH.00145084-088 - Ulmsten, et al - A Multicenter Study of Tension~Free Vaginal Tape (TVT) for Surgical Treatment of Stress Urinary Incontinence (Adkins Trial Exhibit DX24232 (T-884)
ETH.MESH.00147507-509 - Approved September 16, 2008 - Marketing Services
ETH.MESH.00153882-885 - Email from David Robinson to Andrew Meek December 17, 2006 RE: TVT SECUR Conf Call Summary
ETH.MESH.00153967-968 - Email from David Robinson to Dharini Amin November 14, 2006 RE: TVT-S Preceptor Meeting Discussion (Adkins trial exhibit P0127)
ETH.MESH.00158248-253 - Performance Evaluation Test Report: Corporate Product Characterization
ETH.MESH.00159266-369 - Gynemesh PS, Prolene Soft Mesh in the treatment of POP - Pelvic Floor Surgery and Anatomic Dissection Lab
ETH.MESH.00161131-32 - TVT-Innovative Surgical Alternative for the Treatment of Female SUI
ETH.MESH.00163952-960 - Gynecare TVT SECUR* System: Key Technical Points
ETH.MESH.00167104-110 - 2006 Apr 19 - Laser Cut Mesh for Gynecare TVT- CER Laser Cut Mesh
ETH.MESH.00203456 - E-mail from Carol Gillick to others regarding TVT Insert (Adkins Trial Exhibit P0207 (T-3373))
ETH.MESH.00211259-60 - Email string re - TVT Exact IFU
ETH.MESH.00214524-529 - Email from Quentin Manley to Barbara Schwartz December 2, 2005 RE: TVT SECUR Minutes - Team Meeting November 22nd 2005_ Agenda November 29th 2005
ETH.MESH.00220335-36 - 12.2.1999 Memo re: Biocompatibility Risk Assessment for Soft Prolene Mesh.
ETH.MESH.00259473-503 - Exhibit T-254
ETH.MESH.00260591-592 - Dan Smith Email Plaintiff's Exhibit 180
ETH.MESH.00262015-016 - Dan Smith Email Plaintiffs Exhibit 2067
ETH.MESH.00267733-872 - (12.12.2006) Lightning Project Charter
ETH.MESH.00271215-216 - Email from J. Meek to multiple recipients re: Pre-Reading for Prolift+M: Internal Use Only. Not Copy Reviewed or For Distribution
ETH.MESH.00273967 - Email from Clifford Volpe to Scott Jones re: slides for Pelvic Floor Summit.; Powerpoint: R&D Perspective - The Journey from Prolift to Prolift +M.
ETH.MESH.00274015 - Krofta Presentation - One year prospective follow-up of the TVT-S Procedure for treatment of stress urinary incontinence (Engleman Trial Exhibit P0238)
ETH.MESH.00281482-484 - Aaron Kirkemo email to Harel Gadot, et al., re Prosima feedback (Engleman Trial Exhibit P0241)
ETH.MESH.00295355 - Gynecare TVT Exact Profession Education Slide Deck.
ETH.MESH.00303084-85 - Email string re-Complaint Summaries
ETH.MESH.00308094 - Gynecare TVT SECUR* System Tension-free Support for Incontinence
ETH.MESH.00308557-577 - LPT Report No. 19284/05
ETH.MESH.00309254-350 - Technical File Amendment - Laser Cut Mesh Product Code 830041BL. September 12, 2006
ETH.MESH.00311778-782 - E-mail chain, top one from Aran Maree to Catherine Beath, Darryl Harkness, et al. regarding Meeting with Austrian Regulator to discuss TVT Secur performance; cc: David Robinson, et al. (T-904) (Adkins Trial Exhibits DX24297R)
ETH.MESH.00311792-794 - E-mail from Aran Maree to Fiona Smith regarding Australia update and telephone call with Prof Frazer (T-909) (Adkins Trial Exhibit P0254 (Redacted) (Adkins Trial Exhibits DX24681)
ETH.MESH.00311819-820 - Email from David Robinson to Dan Smith March 1, 2007 RE: User Recommendation for TVT Secur

**Production Materials**

ETH.MESH.00312179-182 - Email from Catherine Beath to Aran Amree November 2, 2007 RE: Meeting with the Australian Regulator to discuss TVT Secur performance
ETH.MESH.00318306-307 - Email from Mark Yale to Aran Maree February 6, 2008 RE: Discussion Minutes: TVT-Secur follow up with Australia Discuss
ETH.MESH.00318316-317 - Depo Ex. 5 to the Deposition of Aran Maree taken on 07.23.13 - Email string, top one from Aran Maree to Christiana Bielinski, et al. re: TVT Secure Slide set. (Adkins Trial Exhibits DX24546R)
ETH.MESH.00318738-748 - Email from Mark Yale to Luis Blanco June 20, 2008 RE: URGENT: Medical Devices Vigilance System - TVT Secur complaint, our file #10100067834 (torn mesh), Filr # 10100068332 (hematoma)
ETH.MESH.00321804-805 - Definition for MAJOR INVASIVE SURGERIES And The Ethicon Franchise Products Requiring Major Invasive Procedures for Implantation (Adkins Trial Exhibit P0269)
ETH.MESH.00324086-088 - Email from Carolyn Brennan to Luis Blanco January 22, 2007 RE: Complaints TVT Secur - Germany
ETH.MESH.00324109 - Carolyn Brennan email to Mark Yale dated 11.02.2006 re TVT-S difficulties with insertion of device (Engleman Trial Exhibit P0274)
ETH.MESH.00326211-213 (Adkins trial exhibit P0279)
ETH.MESH.00326756 - PowerPoint presentation entitled "TVT-SECUR PQ107-041, Quality Board Follow Up" (Adkins Trial Exhibits DX24307)
ETH.MESH.00326842-846 - Catherine Beath email to Sheri McCoy and Renee Selman dated 11.05.2007 re urgent meeting with Australian _____ to discuss TVT Secur performance - includes email from Aran Maree dated 11/2/2007 re Australian launch of TVT S (Engleman Trial Exhibit P0286)(Adkins Trial Exhibit P0286)
ETH.MESH.00327060-063 - Robinson email (Dr. Aran Maree) chain dated 11.12.2007 re Dr. Frazier's (Australia) opinions re TVT-S (Engleman Trial Exhibit P0290) (Adkins Trial Exhibit P0290)
ETH.MESH.00328895-901 - David Robinson email to Mark Yale and Daniel Lamont dated 03.03.2008 re quality issue with a batch of gynemesh (Engleman Trial Exhibit P0292)(Adkins Trial Exhibit P0292)
ETH.MESH.00328977 - Email from Renee Selman to Mark Yale March 20, 2007 RE: Conflict with Town hall
ETH.MESH.00329001-002 - Agenda & Minutes; TVT-Secur PQ107-041 Quality Board November 16, 2007
ETH.MESH.00329316-317 - Email from Mark Yale to David Robinson November 6, 2006 RE: TVT-S Complaint Review
ETH.MESH.00329557-558 - Email from Mark Yale to Sergio Gadaleta March 1, 2007 RE: user recommendation for TVT Secur
ETH.MESH.00330141 - Email from Mark Yale to Konrad Schmitt February 13, 2007 RE: TVT-S
ETH.MESH.00330408 - Email from Mark Yale to Ted Foltyn November 15, 2007 RE: TVT-S in Australia
ETH.MESH.00330962-964 - Email from Christiana Bielinski to Aran Maree February 26, 2008 RE: FW: Communication to Surgeons Regarding the Gynecare TVT Secure System No Protective Marking - SEC=UNCLASSIFIED]
ETH.MESH.00332958 - Email from Patty Lancos to Jackie Sauer August 27, 2008 RE: PQI on TVT-S
ETH.MESH.00333695-696 - Email from Cheryl Bogardus to Dan Smith April 3, 2007 RE: TVT-S
ETH.MESH.00334646-647 - Email from Jonathan Meek to Mark Yale January 9, 2008 RE: TGA Meeting
ETH.MESH.00339437-42 - Gynecare TVT - 5 Years of Proven Performance



**Production Materials**

ETH.MESH.00349226-237 - May 26, 2000 Ethicon Memo to P. Cecchini RE: Review of Biocompatibility Data on the Tension Free Vaginal Tape (TVT) System for Compliance to FDA G-95/ ISO 10993/ EN 30993
ETH.MESH.00349228-37 - Ethicon Memo to C. Linsky Re: Cytotoxicity Risk Assessment for the TVT (Ulmsten) Device 8.8.1997
ETH.MESH.00354732 - Gynecare TVT Abbrevio Professional Education.
ETH.MESH.00365412-414 - June 14, 2007 Memo RE: ADDENDUM: Post - Launch Complaint Review for the PROLIFT* Pelvic Floor Repair System
ETH.MESH.00365960-965 - Gynecare TVT Secur System Procedural Pearls & Frequently Asked Questions.
ETH.MESH.00369995 - Treatment of Stress Urinary Incontinence with the Gynecare TVT Family of Products.
ETH.MESH.00369999 - Treatment of Stress Urinary Incontinence with GYNECARE TVT SECUR* System
ETH.MESH.00370392 - GYNECARE TVT SECUR* System Early Surgical Experience
ETH.MESH.00372341-357 - Letter from B. Lisa to J. Dang reL K071512 S02 (09.20.2007)
ETH.MESH.00372664-671 - Letter from B. Lisa to J. Dang re: K071512 S04. (02.21.2008)
ETH.MESH.00373310 - Gynecare TVT Tension-Free Support for Incontinence: General Profession Education Deck.
ETH.MESH.00395374-380 - Scientific Advisory Panel on Pelvic Floor Repair Preliminary Minutes Chicago, IL June 22, 2001
ETH.MESH.00403003-017 - Cadaver Protocol/ Competition Report
ETH.MESH.00406656 - March 20, 2009 Letter to Oscar Aguirre RE: TVT WORLD Registry
ETH.MESH.00406790 - March 20, 2009 Letter to Radhika Ailawadi RE: TVT WORLD Registry
ETH.MESH.00406854 - March 20, 2009 Letter to Gunhilde Buchsbaum RE: TVT WORLD Registry
ETH.MESH.00407016 - March 20, 2009 Letter to Denise Elser RE: TVT WORLD Registry
ETH.MESH.00407182 - March 20, 2009 Letter to Nicholas Franco RE: TVT WORLD Registry
ETH.MESH.00407285 - March 20, 2009 Letter to Douglas Grier RE: TVT WORLD Registry
ETH.MESH.00407592 - March 20, 2009 Letter to Michael Karram RE: TVT WORLD Registry
ETH.MESH.00407863 - March 20, 2009 Letter to John Nguyen RE: TVT WORLD Registry
ETH.MESH.00407924 - March 20, 2009 Letter to James Raders RE: TVT WORLD Registry
ETH.MESH.00407950 - March 20, 2009 Letter to Douglas VanDrie RE: TVT WORLD Registry
ETH.MESH.00442831-834 - (01.18.2005) Email string, top one from Kelly Brown to Gene Kammerer, et al. re: Proposal for work with CBAT.
ETH.MESH.00461576 - 10.23.2006 letter to EWHU field sales force
ETH.MESH.00518646-648 - Email from David Robinson to Harel Gadot RE: Clinical Strategy for SECUR June 20, 2006
ETH.MESH.00519476-481 - Email from Dan Smith to Jessica X. Shen December 19, 2006 RE: TVT-S Cookbooks
ETH.MESH.00523617-618 - Summary of Gynecare TVT Secur* System Critical Steps
ETH.MESH.00523942 - Waltregny 2005 ICS Presentation
ETH.MESH.00526473-74 - Allison Brown Email re-Laser-cut Mesh
ETH.MESH.00526773-774 - 5/11/06 Ethicon Women's Health & urology Gynecare TVT Secur Press Release Questions & Answers
ETH.MESH.00527118-121 - Email from Joy Hovespian to Dharini Amin August 28, 2007 RE: FW: Dr. Sepulveda's notes summary/PLEASE DO NOT DISTRIBUTE. JUST FOR INTERNAL REVIEW
ETH.MESH.00527624-629 - Email from Dan Smith to David Robinson March 9, 2007 RE: DRAFT of the latest "cookbook" after my trip to Germany

**Production Materials**

ETH.MESH.00527802 - Email from David Robinson to Dharini Amin April 22, 2007 RE: Secur video
ETH.MESH.00527808-811 - Email from Dharini Amin to Harel Gadot May 17, 2007 RE: TVT SECUR EU Experts meeting - feedback & future actions
ETH.MESH.00527824-827 - Email from Axel Arnaud to Dharini Amin May 21, 2007 RE: TVT SECUR EU Experts Meeting - Feedback & Future Actions
ETH.MESH.00527832-836 - Email from Dan Smith to Harel Gadot May 22, 2007 RE: TVT SECUR EU Experts meeting - feedback & futures actions
ETH.MESH.00528121 - Talking Points for Clinical Plan for Gynecare TVT Secur® System
ETH.MESH.00528140 - Email from David Robinson to Linda Linton September 7, 2006 RE: TVT SECUR convention panel for reps
ETH.MESH.00528157 - Email from David Robinson to Sergio Gadaleta September 7, 2006 RE: Less Dissection
ETH.MESH.00528168-171 - Email from Dan Smith to Axel Arnaud December 18, 2006 RE: TVT-S Cookooks
ETH.MESH.00528179 - Email from David Robinson to Bob Roda December 29, 2006 No Subject
ETH.MESH.00528184-185 - Minutes TVT Secur resolution team First meeting 1/22/07
ETH.MESH.00528255 - A Multi-Centre, Open-Label, Randomized, Non-Comparative Study Designed to Obtain Clinical Information on the TVT-Secur System. 5-week results. D Robinson, MD
ETH.MESH.00528772-773 - Memo from Gary Borkes to TVT Secur eDHF #0000120 regarding TVT Secur 12 month Post Launch Review (Adkins Trial Exhibits DX24322)
ETH.MESH.00529863 - Chart listing type of study, protocol #, protocol nickname, protocol title and investigators.
ETH.MESH.00533250-256 - TVT-World-Wide Observational Registry for Long-Term Data TVT-World Protocol: 300-06-006 Protocol Amendment 2: April 28, 2009 Summary of Changes: 11-21
ETH.MESH.00533283-286 - Communication Plan to Close TVT WORLD Registry
ETH.MESH.00533285-286 - Timelines for communicating information to investigators
ETH.MESH.00539862-869 - TVT-World-Wide Observational Registry for Long-Term Data TVT-World Protocol 300-06-006
ETH.MESH.00541187-190 - Email from Carolyn Brennan to Joseph Scavona September 11, 2009 RE: TVT Secur Inserter Heads Up
ETH.MESH.00541379- Memo to File RE: Mesh Draying for TVT Devices 11.18.03
ETH.MESH.00541379-80 - Mesh Fraying for TVT Devices
ETH.MESH.00572598 - TVT-Secur: European Feedback Powerpoint Presentation (Adkins Trial Exhibit P0399) (Adkins Trial Exhibits DX24679 (T-891)
ETH.MESH.00575257 - Abbrevio laser cut vs. mechanically cut - notes from meeting with de leval - inappropriate
ETH.MESH.00575270-273 - Jean de Leval Email Re: DSCN3332.JPG May 30, 2009
ETH.MESH.00576725-726 - MAUDE Review; Overall TVT Powerpoint
ETH.MESH.00584811-13 - Email string re-Ultrasonic Slitting of Prolene Mesh for TVT
ETH.MESH.00584846-847 - (05.10.2004) Email string, top one from Gene Kammerer to Mora Melican, et al. re: Mesh for TVM.
ETH.MESH.00584847 - (05.10.2004) Email string, top one from Gene Kammerer to Mora Melican, et al. re: Mesh for TVM.
ETH.MESH.00585229 - (01.14.2005) Email from Gene Kammerer to Dr. Dieter Engel re: UltraPro for Pelvic floor repair.
ETH.MESH.00585688-690 - Use of UltraPro Mesh for Pelvic Organ Prolapse (POP) Repair through a Vaginal Approach.

**Production Materials**

ETH.MESH.00585937-939 - (02.13.2006) Email string, top one from Gene Kammerer to Quentin Manley, et al. re: TVM discussions.
ETH.MESH.00589602-607 - Teo R, et al. Randomized Trial of Tension-Free Vaginal Tape and Tension-Free Vaginal Tape-Obturator for Urodynamic Stress Incontinence in Women. Journal of Urology 2011; 185:1350-1355.
ETH.MESH.00589602-607 - Teo, R. Randomized Trial of Tension-Free Vaginal Tape and Tension-Free Vaginal Tape-Obturator for Urodynamic Stress Incontinence in Women. Journal of Urology 2011; 185: 1350-1355
ETH.MESH.00590896-897 - Piet Hinoul Email 3.11.09
ETH.MESH.00596225 Sikirica, V., et al. A systematic review of the Gynecare prolift pelvic floor repair system in pelvic organ prolapse. Int Urogynecol J (2010).
ETH.MESH.00596558-560 - Email from Dan Smith to Aaron Kirkemo RE: FW: Scion PA commercial recommendation
ETH.MESH.00642325-331 - Email from Kevin Mahar to Ted Foltyn October 29, 2007 RE: TVT-O Versus TVT Secur efficacy and safety rates (Adkins trial exhibit P0429)
ETH.MESH.00642393-399 - Email from Kevin Mahar to Ted Foltyn October 28, 2007 RE: TVT-O Versus TVT Secur efficacy and safety rates
ETH.MESH.00656714-716 - Email from O. Berthier to multiple recipients re: Update on Prolift CD rom
ETH.MESH.00658177-198 - Surgeons Resource Monograph
ETH.MESH.00687819-22 - Email string re-Laser cut mesh
ETH.MESH.00719198-209 - (02.06.2007) Email string, top one from Kevin Mahar to Linwood Staub re: ACOG Practice Bulletin on Pelvic Organ Prolapse.
ETH.MESH.00719241-242 - Draft for review. 2/05/07 Standby Statement
ETH.MESH.00742137-139 - Email from Dharini Amin to Joy Hovsepian March 13, 2007 RE: TVT-Secur v. BSX Prefyx PSS
ETH.MESH.00746179-180 - Email from Harel Gadot to Evridiki Kakoliri September 14, 2006 RE: TVT SECUR Launch activities
ETH.MESH.00746181-182 - Hold for Release Until 9/05/06, 8 a.m. EST Ethicon Introduces New Device to Treat Stress Incontinence
ETH.MESH.00816278 - Email from Lissette Caro-Rosado to Bart Pattyson September 29, 2009 RE: Professional education for TVTS
ETH.MESH.00823138 - Finnegan, S. Clinical outcome of the first cases of the TVT secur in the UK
ETH.MESH.00823421-422 - Gynecare TVT SECUR* System - Australian Postmarket Surveillance Review Meeting October 31st, 2007 (T-901) (Adkins Trial Exhibits DX24259R)
ETH.MESH.00823549 - Application FMEA for TVT Secur
ETH.MESH.00831102-110 - Review TVT-Secur versus MiniArc: PUBMED published data - updated July 6, 2010
ETH.MESH.00832121-124 - Email from Mark Yale to Ricci Whitlow November 2, 2007 RE: Meeting with the Australian Regulator to discuss TVT Secur performance
ETH.MESH.00832226-229 - Email from Mark Yale to David Robinson November 12, 2007 RE: Australia update and telephone call with Prof Frazer
ETH.MESH.00832318 - Email from Axel Arnaud to Christophe Mauge July 17, 2007 RE: Dr. VARMA (UK)
ETH.MESH.00833931-932 - Email from David Robinson to Sharon Shantz January 29, 2007 RE: GYNECARE TVT
ETH.MESH.00834435 - First Human Data for TVT-SECUR* System Support of Life-Cycle Powerpoint

**Production Materials**

ETH.MESH.00835753-755 - (11.30.2006) Email string, top one from David Robinson to Clifford Volpe re: changes Cosson and Jacquetin want made to Prolift.
ETH.MESH.00836558-59 - Email string re - TVT-O groin pain
ETH.MESH.00839446-459 - August 23, 2005 Final Report, PSE Accession Number 05-0395, PROJECT Number 67379
ETH.MESH.00839908 - Email from Harel Gadot to Bruno Delacroix August 28, 2006 RE: Prof. Nilsson - TVT SECUR
ETH.MESH.00839918-19 - Email from David Robinson September 20, 2006 RE: TVTS Complaint up to 20 September 06.ppt
ETH.MESH.00840018 - Email from Axel Arnaud to David Robinson December 19, 2006 RE: TVT Secur
ETH.MESH.00840056 - TVT SECUR YTD Findings
ETH.MESH.00842256-257 - Email from David Robinson to Joel S. Lippman December 5, 2005 RE: TVT S design val
ETH.MESH.00844901-902 - Email from David Robinson to Kevin Mahar October 18, 2007 RE: Updated Presentation for NPD Meeting - TVT SECUR
ETH.MESH.00845535-536 - Email from David Robinson to Ted Foltyn November 24, 2007 RE: SECUR AU Discussion (Adkins Trial Exhibits P0523 (Redacted))
ETH.MESH.00845669-670 - Ethicon Memo December 4, 2007 RE: PQI-07-043 TVT Secur release mechanism
ETH.MESH.00846478-479 - Email from David Robinson to Dharini Amin March 13, 2007 RE: TVT- Secur v. BSX Prefyx PSS
ETH.MESH.00848473-474 - Email from David Robinson to Harel Gadot January 10, 2007 RE: Report from Austria
ETH.MESH.00851319-321 - Email string, top one from P. Hinoul to C. Volpe, et al. re: Prosima implant dimensions.
ETH.MESH.00855158-159 - (12.17.2007) Email from Peter Meier to Clifford Volpe, et al. re: Explant database for Pelvic Floor Meshes.
ETH.MESH.00855459 - TVT-Secur (hammock) versus TVT-Obturator: A randomized trial of suburethral sling operative procedures
ETH.MESH.00857821 - Top Ten Reason to pursue Gynecare TVT Obturator System
ETH.MESH.00858080-081 - Perry Trial - Plaintiff's Exhibit 2313
ETH.MESH.00858094-95 - Gynecare R&D Monthly Update - March
ETH.MESH.00858096-97 - Gynecare R&D Monthly Update - May
ETH.MESH.00858175-176 - Mulberry Weekly Meeting MINUTES for 6.3.03
ETH.MESH.00858252-53 - 2004 Memo from London Brown to Dan Smith re Mechanical Cut vs. Laser Cut Mesh Rationale (Adkins trial exhibit P0542)
ETH.MESH.00858636-641 - Memo to Dan Smith, Ed Bobertz, Dharini Amin RE: TVT SECUR Lessons Learned Review
ETH.MESH.00858786-787 - Memo to File: Capa #xyz RE: Documentation of the steps taken to understand and resolve issues on TVT SECUR post launch concerns
ETH.MESH.00860142-144 - Email string re-Sample Media TVTO
ETH.MESH.00862176-185 - Prolene Revision History for MS-729-001
ETH.MESH.00862754-757 -6.9.03 Dan Smith Email Re: Double Edged Sword
ETH.MESH.00863391 - T-366 - Dan Smith email - particle loss
ETH.MESH.00870466-476 - (06.02.2006) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.
ETH.MESH.00872132-136 - Email from Dan Smith to Mark Yale September 15, 2006 RE: Potential quality issue on TVT-S

**Production Materials**

ETH.MESH.00873965-966 - Email from Mark Yale to Gary Borkes December 18, 2009 RE: FW: TVT-S Compliant Review
ETH.MESH.00874280 - Email from Mark Yale to Laurent Soulier September 21, 2006 RE: Potential quality issue on TVT-S
ETH.MESH.00874339-340 - Email from Dan Smith to Hanke Sierk March 6, 2007 RE: TVT-Secur CAPA
ETH.MESH.00874349-351 - Email from Dan Smith to Harel Gadot May 29, 2007 RE: TVT SECUR
ETH.MESH.00874445-476 - PowerPoint presentation entitled "TVT-SECUR PQ107-041, Quality Board, 16 Nov 2007" (Engleman Trial Exhibit P0581) (Adkins Trial Exhibit P0581 (T-3132)
ETH.MESH.00874516 - Email from Mark Yale to Catherine Beath November 26, 2007 RE: TVT-S Update
ETH.MESH.00874519-520 - Email from Dan Smith to Mark Yale November 26, 2007 RE: TVT-S Update (Adkins Trial Exhibits P0584 (Redacted)
ETH.MESH.00874627-629 - Email from David Robinson to Mark Yale January 7, 2008 RE: SECUR Markets: TVT SECUR - Critical Steps Guide
ETH.MESH.00875656-657 - Email from Quentin Manley to Mark Yale December 21, 2005 RE: Minutes of meeting: TVT SECUR design validation discussion 20 <sup>th</sup> Dec 2005
ETH.MESH.00911305 - Memo re: PDD Requirement 2.3.2 pertaining to clinical evidence (11.22.2004).
ETH.MESH.00918015 - Sunoco MSDS 04.13.05
ETH.MESH.00922443-446 - Email string, top one from P. St. Hilaire to B. Lisa, et al. re: Bidirectional elasticity statement
ETH.MESH.00989774-775 - History of TVM, Development of the Technique.
ETH.MESH.00993273 - TVT Obturator Anatomic Considerations Clinical Update: Special Considerations, Complications.
ETH.MESH.00994917-18 - McCabe email re - Sheath Sales Tool
ETH.MESH.01000254-257 - Email from David Robinson to Cheryl Bogardus March 7, 2007 RE: FW: DRAFT of the latest "cookbook" after my trip to Germany
ETH.MESH.01000635-636 - Email from Sergio Gadaleta to John Clay September 6, 2006 RE: FINAL REVISED TVT SECUR Flash Animation Home Page (2696) - For FINAL SIGN OFF
ETH.MESH.01000726-730 - Email from Axel Arnaud to Dan Smith December 19, 2006 RE: TVT-S Cookbooks
ETH.MESH.01000731-735 - David Robinson email to Axel Arnaud and Dan Smith dated 12.19.2006 re TVT-S Cookbooks (Engleman Trial Exhibit P0619) (Adkins Trial Exhibit P0619 (T-860)
ETH.MESH.01037447-455 - Charlotte D. Owens Clinical Report on TVT-S
ETH.MESH.01059148-152 - Gynecare TVT-Secur 2007 Product Complaints Involving Serious Injury
ETH.MESH.01128679-698 - Brochure - Procedural Steps Gynecare TVT SECUR™ System - The Support is Here
ETH.MESH.01130568 - Ethicon, Inc. Worldwide Complaint-Reporting Statement Gynecare TVT Secur™ System
ETH.MESH.01154031-37 - Clinical Expert Report - Gynemesh Prolene Soft
ETH.MESH.01186550-56 - Rosenblatt, P. Update on suburethral slings for stress urinary incontinence.
ETH.MESH.01189392-395 - Summary of sheep and human cadaver labs for development of the GYNECARE TVT SECUR* System
ETH.MESH.01189423-439 - Martin Weisberg; Dave Robinson Clinical Report on TVT-S 2.28.06
ETH.MESH.01193925-930; ETH.MESH.0100644-645 - TVT-Secur: "Hammock" position; Minutes regarding events with Dr. Folke Flarn and training

**Production Materials**

ETH.MESH.01193957-971 - Executive Summary Preliminary Results of Peri-Operative and 3-Month Outcomes from a world-wide observational registry of tension-free Vaginal Tapes in women with stress urinary incontinence
ETH.MESH.01193973 - A multicenter, Open-Label, Randomized, Non-Comparative Study Designed to Obtain Clinical Information on the GYNECARE TVT SECUR* System Tension-free Support for Incontinence 5 week results. David Robinson, MD Medical Director, ETHICON Women's Health & Urology
ETH.MESH.01202101-03 - Email string re - Revised writeup of the DeLeval and Waltregny visit
ETH.MESH.01202189 - Stale Kvitle Email regarding Mini Me follow up from our visit May 20, 2009
ETH.MESH.01202190-191 - David Waltregny Email Re: Mini Me follow up from our visit May 21, 2009
ETH.MESH.01203847-869 - Performance Evaluations of A New TVT Single Incision Mesh System for the Treatment of Stress Urinary Incontinence. Daniel J. Smith; Engineering Fellow Ethicon's Women's Health and Urology
ETH.MESH.01203957-97 - The future of surgical meshes-the industry's perspective
ETH.MESH.01215019-24 - Tseng LH, et al. Randomized comparison of the suprapubic arc sling procedure vs TVT for stress incontinent women. Int Urogynecol J (2015) 16:230-235.
ETH.MESH.01216820-822 - Email from Dan Smith to Aaron Kirkemo March 23, 2010 RE: Information Regarding Scion
ETH.MESH.01218019 - Design FMEA TVT LCM Project
ETH.MESH.01218423-424 - Pelvic Organ Prolapse Repair: Lesson Learned from the Prolift Experience.
ETH.MESH.01219542-48 - Review of Surgeon Responses of VOC Questionnaire
ETH.MESH.01220135-45 - Email string re-New Standards for Urethral Slings
ETH.MESH.01221055-58 - Pariente J-L. An Independent biomechanical evaluation of commercially available suburethral slings- 8.5% particle loss.
ETH.MESH.01222617-54 - Protocol PSE Accession NO. 02-0579-T-2176
ETH.MESH.01228079-84 - Nilsson Podcast Transcript
ETH.MESH.01238454-56 - Email string re-TVTO length
ETH.MESH.01239657-680 - First Clinical Experience with a Single-incision (TVT Secur®) Tape Procedure for Treatment of Urinary Stress Incontinence
ETH.MESH.01264260 - Prolift +M Piet Hinoul Pelvic Floor Meeting Nderland Utrecht, May 7, 2009
ETH.MESH.01271289-301 - Gynecare TVT with Abdominal Guides Early Clinical Experience
ETH.MESH.01274741-743 - Use of UltraPro Mesh for Pelvic Organ Prolapse (POP) Repair through a Vaginal Approach.
ETH.MESH.01279975-976 - E-mail from Harel Gadot to others regarding Next step in SUI sling (Adkins Trial Exhibits P0686 (T-2040)
ETH.MESH.0128019 - Design FMEA TVT LCM Project
ETH.MESH.01314498-505 - Memo re: Prolift Design Review: Design Verification, Process Qualification and Design Transfer - Review Minutes and Action Items (02.28.2005).
ETH.MESH.01317508-613 - TVT Factbook DHF - Revised 05.14.2001
ETH.MESH.01317515-524 - TVT Preventia FMEA [T-2143]
ETH.MESH.01407852 - Ethicon Sarl, Neuchatel Potential Failure Mode and Effects Analysis Process FMEA
ETH.MESH.01409306-348 - Form for Design Requirements Matrix
ETH.MESH.01424029-35 - Cobb WS, et al. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation, Vol 12, No 1 (2005)



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ETH.MESH.01428106-112 - Carvigni, M. The use of synthetics in the treatment of pelvic organ prolapse. Curr Opin Urol 2001; 11: 429-435.
ETH.MESH.01592121-134 - Gynecare TVT Secur* System Design Validation Report (Product) Report #TVTSDVLPRD1
ETH.MESH.01687850 (Adkins trial exhibit P4127)
ETH.MESH.01716847-848 - (03.20.2007) Email string, top one from Bart Pattyson to Dr. Hilary Cholhan re: response to ACOG bulletin.
ETH.MESH.01733531-535 - Kasturi, S. Pelvic magnetic resonance imaging for assessment of the efficacy of the Prolift system for pelvic organ prolapse. Am J Obstet Gynecol 2010; 203: 1.e1-1.e5
ETH.MESH.01736775-791 - Martin Weisberg; Dave Robinson Clinical Report on TVT-S 2.20.06
ETH.MESH.01739544-579 - Clinical Evaluation Report Gynecare (Tension-free Vaginal Tape) TVT Secur* System by David Robinson November 1, 2010
ETH.MESH.01744577-582 - Memo from Dan Smith to Dr. David Robinson RE: Elongation Characteristics of Laser Cut PROLENE Mesh for TVT SECUR February 15, 2006
ETH.MESH.01746858-861 - Email from Harel Gadot to Andrew Beveridge October 1, 2008 RE: TVT World Registry
ETH.MESH.01752532-535 - Jurgen Trzewik memo re mesh design argumentation issues (Engleman Trial Exhibit P0705)(Adkins Trial Exhibit P0705)
ETH.MESH.01758770-801 - TVT Secur Quality Board powerpoint (Engleman Trial Exhibit P0706)(Adkins Trial Exhibit P0706)
ETH.MESH.01760362-363 - Email from Michael Woods to David Robinson December 21, 2007 RE: Trial
ETH.MESH.01760853-861 - Clinical Expert report (not signed): UltraPro Mesh for Pelvic Organ Prolapse through a Vaginal Approach.
ETH.MESH.01761352-359 - Email from David Robinson to Bob Roda December 20, 2006 RE: TVT-S Cookbooks
ETH.MESH.01761400-403 - Email from David Robinson to Bob Roda May 10, 2007 RE: RECENT AAVIS MESH USERS FORUM/ TVT REIMBURSEMENT UPDATE (Australia)
ETH.MESH.01763770-772 - Email from David Robinson to Dan Smith September 25, 2006 RE: email
ETH.MESH.01767788-789 - Summary of Preliminary Clinical Results for TVT Secur® System
ETH.MESH.01769881 - Letter to Team RE: Reviewing the Last iteration of the Clinical Strategy for TVT Secur
ETH.MESH.01770534 - E-mail from Axel Arnaud to David Robinson and Dan Smith regarding TVT-S Cookbooks (Adkins Trial Exhibit P0709 (T-857)
ETH.MESH.01774812-813 - Meeting Report December 19, 2007 An invention concerning "A lifting thread and technique for percutaneous modeling of soft tissues"
ETH.MESH.01775486-493 - Email from Harel Gadot to Cheryl Bogardus January 8, 2007 RE: TVT-S Cookbooks
ETH.MESH.01777030-036 - Email from David Robinson to Judith Gauld June 20, 2007 RE: Drafted Standard for SUI Slings and POP/AFNOR/ France
ETH.MESH.01782114-115 - (05.03.2006) Email string, top one from David Robinson to Carolyn Brennan re: Suzette email discussing problems with Prolift.
ETH.MESH.01782783-785 - (02.02.2006) Notes from meeting with Dr. V. Lucente and Dr. M. Murphy (Allentown, PA) to discuss Prolift RCT.
ETH.MESH.01782850-852 - Email from David Robinson to Harel Gadot June 20, 2006 RE: Clinical strategy for SECUR (Adkins trial exhibit P0716)
ETH.MESH.01782854-866 - 2007 ACOG Practice Bulletin No. 79 re: Pelvic Organ Prolapse.

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ETH.MESH.01784428-435 - Email from David Robinson to Allison London Brown December 20, 2006 RE: TVT-S Cookbooks (Adkins Trial Exhibit P0719 (T-863)
ETH.MESH.01784823-28 - Clinical Expert report-Laser Cut Mesh
ETH.MESH.01785259-260 - (01.17.2010) Email string, top one from Piet Hinoul to David Robinson, et al. re: Prolift+M relaxation.
ETH.MESH.01802785-786 - TVT Secur, Confirmation lab - Protocol only LAB 5/24/2005
ETH.MESH.01802790-791 - TVT Secur, Confirmation lab - Protocol Only LAB 5/31/2005
ETH.MESH.01808311-318 - Trip Report Michael Tracey
ETH.MESH.01809080 - Email from Beck Leibowitz -- Eth.mesh.01809080 -- "three times stiff than machine-cut mesh" (Adkins Trial Exhibit P0732)
ETH.MESH.01809080-081 - Becky Leibowitz email to Paul Parisi and Dan Smith dated 12.14.2004 re comparison of laser-cut and machine-cut TVT mesh to meshes from competitive devices (Engleman Trial Exhibit P0732)
ETH.MESH.01809082-83 - Memo re: VOC on new laser cut TVT mesh
ETH.MESH.01813259; ETH.MESH.02180759-61 - Email string with attachment re-Jeans Ideas.
ETH.MESH.01813975-78 - Email string re-FDA Prep-Plaintiff's Exhibit 460
ETH.MESH.01815027-029 - Key Human Cadaver Lab Reports used in the development of TVT SECUR
ETH.MESH.01815103-104 - TVT X Cadaver Lab 12/14/2004 (Results are in BOLD)
ETH.MESH.01815105-110 - TVT X, protocol and completion report 12/28/2004
ETH.MESH.01815111-113 - TVT-U (Results) Cadaver Lab 1/28/2005
ETH.MESH.01815114-117 - TVT Secur, Confirmation lab - Report LAB 5/24/2005
ETH.MESH.01815118-120 - TVT Secur, Confirmation lab - Report LAB 5/31/2005
ETH.MESH.01815135-143 - August 10, 2005 Gynecare TVT* Secur Cadaver Protocol
ETH.MESH.01822361-363 - Dan Smith Email regarding TVT Secur leading to less retention October 18, 2006
ETH.MESH.01824316-317 - Email from Dan Smith to Eric Gauthier November 6, 2006 RE: FW: TVT-S Complaint review
ETH.MESH.01824402-407 - Email from Dan Smith to Axel Arnaud December 19, 2006 RE: TVT-S Cookbooks
ETH.MESH.01923497 - August 22, 2008 Memo RE: PQI07-041 Issue: Concerns with J&J Australia in regards to anecdotal reports of high post procedure incontinence - 6wks post op to TVT-SECUR procedure.
ETH.MESH.01946236-238 - Email from Dan Smith to David Robinson Marh 7, 2007 RE: DRAFT of the latest "cookbook" after my trip to Germany
ETH.MESH.01946719-721 - Email from Catherine Beath to Mark Yale November 5, 2007 RE: Additional complaints
ETH.MESH.02001398-404 - Gynecare Prolift IFU (English Only)
ETH.MESH.02017152-158 - (02.23.2007) Ethicon Expert Meeting: Meshes for Pelvic Floor Repair.
ETH.MESH.02026591-95 - MSDS-c4001 Polypropylene Homopolymer
ETH.MESH.02059150-151 - May 24, 2006 Memo RE: First Post - Launch Complaint Review for the PROLIFT* Pelvic Floor Repair System
ETH.MESH.02089443-446 - Meeting of the Group TVM, Paris, September 29, 2013.
ETH.MESH.02090196-209 - Plaintiff's Exhibit 4085-04.15.2008
ETH.MESH.02105223 - Incontinence Platform - WW Marketing Team Update PowerPoint (T-898) (Adkins Trial Exhibits DX24680R; P0784)

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ETH.MESH.02106139-140 - Email from Jason Hernandez to Lesley Fonio February 27, 2009 RE: Regional Input to Finalize TVT WORLD Recommendation for Board Meeting on Monday March 2 <sup>nd</sup> .
ETH.MESH.02134271-73 - Draft-Mechanisms of Cytotoxicity of TVT
ETH.MESH.02136060-073 - Gynecare TVT Secur system design validation report (product) (Engleman Trial Exhibit P0789)
ETH.MESH.02148446-459 - Klosterhalfen, Junge, Klinge. The lightweight and large porous mesh concept for hernia repair (Engleman Trial Exhibit P0791)
ETH.MESH.02151813 - TVT-Secur PQI07-041 Quality Board - Follow Up
ETH.MESH.02168828-831 - Minutes of the second meeting on NICE IP review consultation - TVT SECUR 9 November 2007
ETH.MESH.02180759-761 - University of Liege De Leval Confidential Meeting TVT-O Modifications 3.29.04
ETH.MESH.02194843-847 - Email from David Robinson to Ramy Mahmoud November 3, 2007 RE: URGENT: Meeting with the Australian Regulator to discuss TVT Secur performance
ETH.MESH.02200994-995 - February 16, 2006 Memo to Patricia Hojnoski RE: Biocompatibility Risk Assessment for the 510(k) Submission and the CE Mark Design Dossier of GYNECARE TVT Secur
ETH.MESH.02211890 - Bates stamped non-color version - LNE Pore Size Testing of TVT
ETH.MESH.02211890 - Test Report
ETH.MESH.02211912 - Annex 11: Porosity test on finished product - pelvic floor mesh.
ETH.MESH.02215374-375 - Jacquetin B. Prolene Soft (Gynecare) Mesh for Pelvic Organ Prolapse Surgical Treatment: A Prospective Study of 264 Patients. Abstract 767
ETH.MESH.02215565-567 - Email from Scott Ciarrocca to multiple recipients re: a message from Barbara Schwartz re: Prolift (01.02.2005).
ETH.MESH.02219584 - Scion PA/SUI Treatment Unmet Needs Exploratory Research - Presented January 22, 2010
ETH.MESH.02229063 - Secur placement.wmv
ETH.MESH.02232854-874 - Prolift+M - Advanced User Discussion
ETH.MESH.02233126-187 - Prolift+M Educational Module
ETH.MESH.02234874-910 - Waltregny Presentation- A modified version of GYNECARE TVT™ Obturator System Tension-free Support for Incontinence with a shorter tape and reduced dissection
ETH.MESH.02237103-104 - Gynecare TVT™ Family of Products Tension-free Support for Incontinence.
ETH.MESH.02248778 - Mechanical vs. Machine Cut - January 19, 2005 Prepared by: Allison London Brown, Gene Kammerer
ETH.MESH.02248848 - Gynecare TVT Secur Powerpoint (Engleman Trial Exhibit P0842) (Adkins Trial Exhibit P0842)
ETH.MESH.02249054-077 - September 12, 2005 Memo to Dan Smith RE: Report Amendment 1, PSE Accession Number 05-0396, Project Number 67379
ETH.MESH.02270363-365 - (04.14.2005) Email string, top one from Ophelie Berthier to Scott Ciarrocca, et al. re: TVM group meeting.
ETH.MESH.02270724 - (07.19.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: Gynemesh holding force in tissue.
ETH.MESH.02270766-767 - (11.21.2003) Email string, top one from Michel Cosson to Scott Ciarrocca re: D'Art, risk question.

**Production Materials**

ETH.MESH.02270857-858 - (07.16.2004) Email from Laura Angelini to multiple recipients re: D'Art - Conversation with Prof. Jacquetin.
ETH.MESH.02280771-772 -Email string, top one from S. O'Bryan to S. Ciarrocca, et al. re: D'Art clinical expert report (CE Mark requirement)
ETH.MESH.02282833-834 - Email from S. Bell to multiple recipients re: TVM - First training - key learnings
ETH.MESH.02286052-053 - Email string, top one from S. O'Bryan to S. Ciarrocca re: Prolift IFU
ETH.MESH.02310653 - Selman email with attachment re - Information about FDA notification on use of mesh in pelvic surgery
ETH.MESH.02319312 - Memo re-TVT-base & TVT-O Complaint Review for Laser Cut Mesh Risk Analysis
ETH.MESH.02319408-09 Email from David Robinson to Cyrus Guidry dated 4.17.07 enclosing powerpoint "Factors Related to Mesh Shrinkage - What do we know? A review of literature and internal studies" (Engleman Trial Exhibit P0863)(Adkins Trial Exhibit P0863)
ETH.MESH.02320485-489 - Email from David Robinson to Kevin Mahar January 23, 2007 RE: Portugal and your input regarding the surgical visits.
ETH.MESH.02340331-335 - TVT IFU (12.22.03 to 02.11.05)
ETH.MESH.02340471-503 - TVT IFU (2/11/2005 to 4/7/2006) (Adkins Trial Exhibit P0868 (T-1644)
ETH.MESH.02340568-590 - TVT-Secur Instructions for Use (12/16/2005 to Discontinuance) (Engleman Trial Exhibit P0871) (Adkins Trial Exhibit P0871 (T-853)
ETH.MESH.02340568-591 - TVT Secur IFU
ETH.MESH.02340568-90 - TVT-S IFU
ETH.MESH.02340829-835 - TVT-O IFU - (01.07.04 to 03.04.05)
ETH.MESH.02341203-13 - TVT Abbrevio IFU
ETH.MESH.02341454-459 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341522-527 - Gynecare Prolift IFU (English Only)
ETH.MESH.02341658-664 - Gynecare Prolift IFU (English Only)
ETH.MESH.02342194-196 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342218-220 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342250-252 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02342278-279 - Gynecare Gynemesh PS IFU (English Only)
ETH.MESH.02391355-56 - Miller, D., et al. Prospective clinical assessment of the total vaginal mesh (TVM) technique for treatment of pelvic organ prolapse - 6 and 12 month results.
ETH.MESH.02589032-079 - Powerpoint - Investigating Mesh Erosion in Pelvic Floor Repair Report by Berman, et al. May 18, 2011
ETH.MESH.02592389-390 - Email from David Robinson to David Robinson October 19, 2007 RE: TR: TVT SECUR in the Elderly
ETH.MESH.02594067 - Clinical Outcome of the First Cases of the TVT <i>secur</i> in the UK Dr. S Finnegan, SpR; Dr. P P Fogarty, Cons Ulster Hospital, Belfast
ETH.MESH.02596085 - Letters to the Editor 2010; 1457
ETH.MESH.02596677-678 - Lammerink, E. Short-term outcome of TVT-Secur
ETH.MESH.02596687 - Fischerlehner, G. TVT-Secur System: One year experience.
ETH.MESH.02596702 - TVT-Secur Workshop Dr. Sepulveda MC Erasmus Rotterdam 27/5
ETH.MESH.02596703-704 - TVT-Secur Workshop Dr. Sepulveda 27/5 Procedural Guidelines for Hammock placement
ETH.MESH.02599329-330 - Email from Piet Hinoul to David Robinson August 2, 2010 No Subject

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ETH.MESH.02603812-821 - Dissection Techniques in Transvaginal Pelvic Organ Prolapse Repair with Synthetic Mesh
ETH.MESH.02620914-15 - TVT Issue Report
ETH.MESH.02622276-79 - Issue Report; TVT Retropubic 2001.
ETH.MESH.02654027-028 - TVT-O Issue Report 2006
ETH.MESH.02766191-192 - (01.12.2006) Minutes of telephone conference.
ETH.MESH.02910418-421 - Axel Arnaud Email to Martin Weisberg et al dated 11.26.2002 re mini TVT mesh adjustment (Engleman Trial Exhibit P0933)(Adkins Trial Exhibit P0933)
ETH.MESH.0291609-611 - Clinical Study Report Evaluation of the TVT Secur System for Stress Urinary Incontinence Study Code 300-05-002 12.6 Safety Conclusions - 13 Discussion and Overall Conclusions
ETH.MESH.02916532-541 - Clinical Study Report Evaluation of the TVT Secur System for Stress Urinary Incontinence Study Code 300-05-002 1. Title Page - Page 9 Conclusions
ETH.MESH.02916532-615 - Clinical Study Report - Evaluation of the TVT Secur System for Stress Urinary Incontinence (Engleman Trial Exhibit P0934)(Adkins Trial Exhibit P0934)
ETH.MESH.02923305-306 - (08.15.2005) Email string, top one from Anne Doherty to Kimberly Hunsicker re: Prolift.
ETH.MESH.03086214-219 (Adkins trial exhibit P0946)
ETH.MESH.03172197-198 - Internal email from Harel Gadot to David Robinson dated 06.20.2006 re proposed RCT (Engleman Trial Exhibit P0953)(Adkins Trial Exhibit P0953)
ETH.MESH.03172217 - A Multi-Centre, Open-Label, Randomized, Non-Comparative Study Designed to Obtain Clinical Information on the TVT-Secur System M. Karram, MD
ETH.MESH.03185928-931 - Email from Neil David to Harel Gadot October 26, 2007 RE: NICE IP review on Single Incision Sub-urethral slings (TVT Secur)
ETH.MESH.03208548-549 - Email from Piet Hinoul to Judi Gauld January 28, 2009 RE: TVT WORLD AE Report
ETH.MESH.03208738 - Email from Jason Hernancez to Julie Bird February 25, 2009 RE: Quick Response Needed to Finalize TVT WORLD Recommendation for Board Meeting on Monday March 2 <sup>nd</sup>
ETH.MESH.03208739 - Powerpoint TVT WORLD Registry Maximizing the investment SBT Feb 2009
ETH.MESH.03235997-998 - Email from Judi Gauld to Jacqueline Russo-Jankewiez December 16, 2009 RE: TVT Secur - Media Standby
ETH.MESH.03258782-783 - Email from Aaron Kirkemo to David Robinson May 13, 2009 RE:
ETH.MESH.03259439-40 - 4.24.2009 Gauld email chain re Green Journal
ETH.MESH.03259876-877 - (09.21.2005) Email string, top one from Judith Gauld to Jessica Shen re: TVM 6 month data.
ETH.MESH.03354810-811 - Project D'Art, Clinical Strategy, March 20, 2004.
ETH.MESH.03361293 - Mesh Platform Review: Somerville, November, 2010.
ETH.MESH.03367228-232 - Email from Zeb Viana to Ulrika Kohler December 14, 2009 RE: Danish case
ETH.MESH.03427878-883 - TVT IFU - (11.29.10 to 11.26.14)
ETH.MESH.03458123-38 - TVT Patient Brochure
ETH.MESH.03460813-853 - Prolift Surgeon's Resource Monograph, approved 4.13.2007
ETH.MESH.03463398-407 - Email from Stacy Hoffman to Mary Byerly August 12, 2010 RE: FW: Urogynecological urinary incontinence product contract
ETH.MESH.03495151 - (09.01.2005) Letter (redacted) re: Product: Gynecare Gynemesh, Event Date: 05/2005, Reference #10034737.

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ETH.MESH.03576207-208 - (08.09.2005) Email from Martin Weisberg to Carol Holloway re: File #10034737.
ETH.MESH.03590983-1080 - August 10, 2005 Memo to Dan Smith RE: Protocol, PSE Accession Number 05-0396, Project Number 67379
ETH.MESH.03607148 - William Eshman, Charles Lee & George Petit certificates for GYNECARE TVT Professional Education Program (Adkins Trial Exhibits DX24635)
ETH.MESH.03643186 - Ethicon Women's Health and Urology Brand Equity Study Final Report Powerpoint (Engleman Trial Exhibit P1008) (Adkins Trial Exhibit P1008)
ETH.MESH.03647849-853 - E-mail string from Gary Brooks to Raimo Sump, Patricia Hojnoski, Dan Smith, et al. regarding Design Validation Review Meeting TVT-S (Adkins Trial Exhibits DX24393R)
ETH.MESH.03649244-249 - Risk Management Report TVT SECUR System
ETH.MESH.03667696-704 - Company Procedure for US Regulatory Affairs Review of Promotion and Advertising Materials for Medical Devices.
ETH.MESH.03714002-018 - 12.2.05 Gynecare TVT-Secur Clinical Expert Report (Adkins Trial Exhibit DX24588 (T-3119))
ETH.MESH.03714172-180 - Gynecare TVT Secur Cadaver Protocol (Adkins Trial Exhibit P1030)
ETH.MESH.03714599-614 - Martin Weisberg Clinical Report on TVT-S
ETH.MESH.03715978-79 - Weisberg email re: TVT Question
ETH.MESH.03725540-553 - Memo dated 07.06.2010 re EWHU innovation counsel (Engleman Trial Exhibit P2572)
ETH.MESH.03736120-127 - Gynemesh PS: A New Mesh for Pelvic Floor Repair Early Clinical Experience
ETH.MESH.03751819 - The Science of "What's Left Behind"...Evidence & Follow-Up of Mesh Use for SUI.
ETH.MESH.03845446-450 - Email from Darryl harkness to Aran Maree October 30, 2007 RE: SECUR update presented in a WW Mktg. Meeting (Engleman Trial Exhibit P1063) (Adkins Trial Exhibit P1064)
ETH.MESH.03845464-469 - Email from Aran Maree to Robert Scherini October 31, 2007 RE: SECUR Update presented in at WW Mktg Meeting
ETH.MESH.03903827-829 - Project TVM (Trans Vaginal Mesh)
ETH.MESH.03905472-77 - Email string re-TVT recommendation from Dr. Alex Wang
ETH.MESH.03905619-621 - Email from Martin Weisberg to Patirica Hojnoski September 15, 2005 RE: Clinical Expert Report
ETH.MESH.03905968-975 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03905976-991 - Prolift Patient Brochure: POP, Get the facts, be informed, make your best decision
ETH.MESH.03906037-052 - Prolift Patient Brochure: Treatment Options for POP, stop coping, start living
ETH.MESH.03906976 - Exhibit 2227 - TVOT-04.30.2003-Meeting Report
ETH.MESH.03907468-69 - Second Generation TVT - by Axel Arnaud
ETH.MESH.03910175-177 - E-mail from Axel Arnaud to Marty Weisberg regarding Soft Prolene (Adkins Trial Exhibit P1080 (Redacted))
ETH.MESH.03910183-193 - E-mail chain, top one from Axel Arnaud to Martin Weisberg regarding Soft Prolene (Adkins Trial Exhibit P1081 (T-353))
ETH.MESH.03910418-21 - Email string re-Mini TVT - mesh adjustment
ETH.MESH.03910637-638 - Email string, top one from A. Arnaud to W. Van Dijk re: critical Q&A.



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ETH.MESH.03911107-08 - Email string re-TVT complications (an Prof. Hausler)
ETH.MESH.03911901-910 - Deprest J, et al. The biology behind fascial defects and the use of implants in pelvic organ prolapse repair. Int Urogynecol J (2006)
ETH.MESH.03913310 - An Audit of the Introduction of TVT Secur in Clinical Practice F Marsh, P Assassa
ETH.MESH.03913357-359 - Axel Arnaud Email 5.31.07 Re TVT TVT-O
ETH.MESH.03913367 - Debodinance, P. TVT Secur™: More and more minimal invasive. Preminiraly prospective study on 106 cases.
ETH.MESH.03913371 - Marsh, F. An Audit of the Introduction of TVT Secur in Clinical Practice.
ETH.MESH.03913651-655 - CDMA Europe Meeting Urinary Incontinence Platform (Adkins Trial Exhibit DX21500 (T-3270)
ETH.MESH.03913651-655 - CDMA Europe Meeting Urinary Incontinence Platform Meeting Minutes June 1, 2007
ETH.MESH.03915380 - Axel Arnaud email re Dr. Lucente-TVT Procedure Improvements-Prevention of Overstretching
ETH.MESH.03915588-590 - (04.12.2005) Email string, top one from Gene Kammerer to Ronnie Toddywala, et al. re: Ultrapro.
ETH.MESH.03916905-13 - Plaintiff's Exhibit 3827
ETH.MESH.03917375-378 - (11.26.2002) Email string, top one from Martin Weisberg to Dr. Richard Juraschek, et al. re: Mini TVT - mesh adjustment.
ETH.MESH.03921355-156 - Miller, D. Prospective Clinical Assessment of the Total Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse - 6 and 12 month results.
ETH.MESH.03921482-489 - Email from David Robinson to Cheryl Bogardus December 21, 2006 RE: TVT-S Cookbooks
ETH.MESH.03921499-1500 - Email from David Robinson to Usman Azam December 19, 2006 RE: TVT Secur
ETH.MESH.03921503-504 - Email from David Robinson to Axel Arnaud December 19, 2006 RE: TVT Secur
ETH.MESH.03921603-605 - Email from Dan Smith to David Robinson December 5, 2006 RE: TVT-SECUR Follow Up on Conference call last week
ETH.MESH.03921606-608 - Email from Dan Smith to David Robinson December 5, 2006 RE: TVT-SECUR follow up on conference call last week
ETH.MESH.03921612 - E-mail from Ralf Gotter to Arnaud and Gadot dated 11.30.2006 regarding, "The more procedures the more problems." (Engleman Trial Exhibit P1096) (Adkins Trial Exhibit P1096 (T-855)
ETH.MESH.03921798-799 - Email from Andrew Beveridge to Axel Arnaud October 25, 2006 RE: TVT secure report KOL The Netherlands
ETH.MESH.03921836-838 - Email from Laurent Metz to Sheri Dodd RE: TVT - Secur Registry - Local Activities
ETH.MESH.03922228-230 - Email from Quentin Manley to Dhinagar Subramanian October 25, 2007 RE: NICE IP review on Single Incision Sub-urethral slings (TVT Secur)
ETH.MESH.03922261 - Email from Andrew Beveridge to Ted Foltyn October 3, 2007 RE: AMS Mini Arc
ETH.MESH.03922286-288 - Email from David Robinson to Harel Gadot October 1, 2007 RE: FW: TVT Secur Research
ETH.MESH.03922405 - Email from Andrew Beveridge to Axel Arnaud June 6, 2007 RE: FW: TVT Secur & NICE

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ETH.MESH.03922434-437 - Email from Bob Roda to Dharini Amin May 18, 2007 RE: TVT SECUR EU Experts meeting - feedback & future actions
ETH.MESH.03922483-484 - Email from Andrew Beveridge to DL-JNJFRIS EWHU Umbrellas April 26, 2007 RE: GYNECARE TVT SECUR* System Wins Medical Design Excellence Award
ETH.MESH.03922618-619 - Email from David Robinson to Axel Arnaud March 14, 2007 RE: Conf call tomorrow
ETH.MESH.03922619 - A Multicenter, Open-Label, Randomized, Non-Comparative Study Designed to Obtain Clinical Information on the GYNECARE TVT SECUR* System Tension-free Support for Incontinence 5 weeks results. David Robinson, MD Medical Director ETHICON Women's Health & Urology
ETH.MESH.03922953 - Email from Xacier Buchon to Fabrice Degeneve January 16, 2007 RE: French data on TVT Secur (Adkins Trial Exhibit P1100 (T-876)
ETH.MESH.03923121-122 - Andrew Beveridge email to Julie Hocknell and Axel Arnaud dated 02.20.2008 re trip to Israel (TVT-S complication summary) (Engleman Trial Exhibit P1102)(Adkins Trial Exhibit P1102)
ETH.MESH.03923931-934 - Press Interview, Frankfort, June 9, 2005.
ETH.MESH.03924557-86 - Meshes in Pelvic Floor Repair-Findings from literature review and conversations-interviews with surgeons, June 6, 2000.
ETH.MESH.03930120-123 - Nilsson C. Seven-Year Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence. Obstet Gynecol 2004; 104(6): 1259-62
ETH.MESH.03932909-911 - Axel Arnaud "History of TVT-O" document (Adkins Trial Exhibit DX23293) (Adkins Trial Exhibit DX21500 (T-3270)
ETH.MESH.03932912 - The History of TVT
ETH.MESH.03941623 - de Leval Email RE: TVT ABBREVO ALERT - French and English Email and English Translation Certification Plaintiff's Exhibit 3619- Perry
ETH.MESH.03962244 - July 18, 2011 Letter to Surgeon from Piet Hinoul and Aaron Kirkemo
ETH.MESH.04044797-800 - TVT Update Jacquetin, B - Klute, C - Stanton, S - Ulmsten, U - Success and Complications
ETH.MESH.04048515-420 - KOL Interview with Carl Nilsson re intent for next generation mini sling, intent for 2 distinct devices O and R and breakdown of current TVT-S usage in US (Engleman Trial Exhibit P1128)(Adkins Trial Exhibit P1128)
ETH.MESH.04050265-267 - Hinoul Letter regarding De Leval Meeting - Pain in Adductor in young Active Patients
ETH.MESH.04079609 - Gynecare TVT Abbrevio Professional Education (Dr. Babcock).
ETH.MESH.04081189-190 - Meeting Agenda (T-3322) (Adkins Trial Exhibit DX24672 (T-3322) (Adkins Trial Exhibit P1132 (Redacted)
ETH.MESH.04081301-302 - Memo re: Work in Progress Weekly - Items need attention (Adkins Trial Exhibit P1133 (Redacted)
ETH.MESH.04082973-974 - Possible Complications for Surgeries to Correct Pelvic Organ Prolapse and Stress Urinary Incontinence (T-3321) (Adkins Trial Exhibit DX24671) (Adkins Trial Exhibit P1134)
ETH.MESH.04090133-136 - Email from Meng Chen to Mark Yale November 2, 2007 RE: Meeting with the Australian Regulator to discuss TVT Secur performance
ETH.MESH.04092868-869 - E-mail from Meng Chen to others regarding #10100080654 and TVT IFUs (T-3324) (Adkins Trial Exhibit DX24673) (Adkins Trial Exhibit P1137 (Redacted)
ETH.MESH.04093125 - Meng Chen email to Bryan Lisa dated 11.30.2006 re TVT IFUs on tape extrusion, exposure and erosion (Engleman Trial Exhibit P1139)(Adkins Trial Exhibit P1139)

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ETH.MESH.04094863-864 - 01.29.2009 email from Bryan Lisa to Meng Chen regarding TVT IFUs on tape extrusion, exposure and erosion (Adkins Trial Exhibit P1142 (Redacted))
ETH.MESH.04097335-36 - Meng Chen - Medical Assessment for mesh fraying-Tracking 10100054041
ETH.MESH.04099233-234 - Email from Melissa Day to Luis Blanco September 24, 2008 RE: #1010078150
ETH.MESH.04126728-730 - GYNECARE TVT SECUR system - Postmarket Surveillance Review Meeting (T-903) (Adkins Trial Exhibits DX24417R) (Adkins Trial Exhibit P1156 (Redacted))
ETH.MESH.04126732-734 - Gynecare TVT SECUR* Sytem - Postmarket Surveillance Review Meeting November 1st, 2007
ETH.MESH.04126903-906 - Depo Ex. 2 to the Deposition of Aran Maree taken on 07.23.13 - Email string, top one from Jan Law to Aran Maree, et al. (Adkins Trial Exhibits DX24543)
ETH.MESH.04127054-055 - Email from Teng Chuan Khoo to Aran Maree December 5, 2007 RE: Confidential: Australia TCT Secur Issue - Update
ETH.MESH.04127138-139 - Email from David Robinson to Christiana Bielinski January 9, 2008 RE: TGA Meeting
ETH.MESH.04127238 - Communication to Surgeons Regarding the Gynecare TVT Secur™ System March 25 <sup>th</sup> 2008
ETH.MESH.04127331 - Email from Rosalyn Harcourt to Aran Maree September 24, 2008 RE: TVT Secur - re-training
ETH.MESH.04381806-19 - 1997 Literature Review on Biocompatibility of Prolene Sutures and Implants
ETH.MESH.04384112 - Biocompatibility Risk Assessment for the TVT-L Device - June 6, 2001
ETH.MESH.04385209 - October 17, 2005 Memo to Patricia Hojnoski RE: Biocompatibilityand Clinical Risk Statement for the inadverten implantation of the protective cap of GYNECARE TVT Secur in patients
ETH.MESH.04385229-245 - Gynecare Clinical Expert Report - Gynecare TVT Secur System (Adkins Trial Exhibit P1177(T-345))
ETH.MESH.04474756-760 - Hota, et al. (2012) TVT Secur (Hammock) versus TVT Obturator: a randomized trial of suburethral sling operative procedures, Female Pelvic Medicine & Reconstructive Surgery, Volume 18, Number 1, January/February 2012 (Engleman Trial Exhibit P1185)(Adkins Trial Exhibit P1185)
ETH.MESH.04499678 - Confidential Interim Statistical Report dated 9/17/2006 (Adkins Trial Exhibit P0036)
ETH.MESH.04532721-724 - Email from Meng Chen to Carolyn Brennan March 6, 2007 RE: PC# 10100044235 - Dr. [Redacted] (USA - SECUR*) RE: Physician Follow up Request
ETH.MESH.04551757-795 - Email from P. Hinoul to J. Hammond, et al. re: benefit risk profile for TVM
ETH.MESH.04552528-529 - Email from P. Hermansson to multiple recipients re: FDA Health Notification relating pelvic floor repair mesh kits
ETH.MESH.04554734-737 - Letter to Catherine Beath from Thomas Gross RE: Post market Surveillance (PS) Study: PS120095 Trade Name: GYNECARE TVT SECUR SYSTEM 510(K) Number: K052401. Stamped January 3, 2012
ETH.MESH.04558399-409 - Iglesia C. Vaginal Mesh for Prolapse: A Randomized Controlled Trial. Obstet Gynecol 2010;116:293-303
ETH.MESH.04567675 - Ethicon Gynecare US Commercialization Decision Customer Letter 5/15/2012 from Piet Hinoul and Matt Henderson

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ETH.MESH.04567676 - Ethicon Gynecare US Commercialization Decision Distributor Letter 5/15/2012 from Matt Henderson
ETH.MESH.04567677-679 - Ethicon Gynecare US Commercialization Decision Frequently Asked Questions 5/15/2012
ETH.MESH.04567680-681 - Ethicon Gynecare US Commercialization Decision Message from Laura Angelini to Internal WW Associated 5/15/2012
ETH.MESH.04568045 - Letter to Surgeons 6/5/2012 from Piet Hinoul and Matt Henderson
ETH.MESH.04925687-689 - Email from Catherine Beath to Brian Kanerviko January 10, 2012 RE: 522 Order for Surgical Mesh
ETH.MESH.04925709 - Email from Laura Vellucci to Brian Kanerviko January 3, 2012 RE: 522 Guidance Document
ETH.MESH.04929923 - September 22, 2011 Letter to Surgeon from Piet Hinoul and Aaron Kirkemo
ETH.MESH.04938298-299 - Piet Hinoul Email Re: Prof. de Leval - TVT Abbrevio
ETH.MESH.04941016 - Lightweight Mesh Developments (Powerpoint)
ETH.MESH.04945231-239 - (04.14.2005) Email string, top one from Dr. Joerg Holste to Thomas Barbolt, et al. re: UltraPro vs Prolene Soft Mesh.
ETH.MESH.04945231-239 - Email string re-Ultrapro vs Prolene Soft Mesh
ETH.MESH.04945496 - Bernd Klosterhalfen Email Re: Ultrapro vs. Prolene Soft Mesh April 18, 2005
ETH.MESH.05133297 - Email from Sheri Dodd to Laurent Mets December 1, 2008 RE: TVT Value Dossier for Emerging Markets
ETH.MESH.05208563-565 - Email from Teng Chuan Khoo to Sateesh Yalisetti October 25, 2007 RE: TVT-O Versus TVT Secur efficacy and safety rates
ETH.MESH.05208566-569 - Email from Teng Chuan Khoo to Aran Maree October 25, 2007 RE: TVT-O Versus TVT Secur efficacy and safety rates
ETH.MESH.05217098-100 - Modified Prolene Mesh Clearance Letter
ETH.MESH.05217103-144 - Modified Prolene Mesh 510(k)
ETH.MESH.05217145-149 - Flow chart re: Gynecare Prolift
ETH.MESH.05225380-384 - TVT IFU - (09.08.00 to 11.26.03)
ETH.MESH.05234758-762 - Dr. Kerstein Sychaj memo dated 12.12.2006 re State of the knowledge in "mesh shrinkage" - what do we know? (Engleman Trial Exhibit P1235)(Adkins Trial Exhibit P1235)
ETH.MESH.05243256-259 - (11.09.2005) Email string, top one from Gene Kammerer to Dr. Dieter Engel, et al. re: Gynemesh PS w/Monocryl.
ETH.MESH.05246116-122 - Email from Dan Smith to Allison London Brown January 3, 2006 RE: Results of TVTx preclinical trial
ETH.MESH.05315240-65 - 28 Day Rat Study
ETH.MESH.05316775-812 - Report, PSE Accession NO. 02-0579-T-2133
ETH.MESH.05337217-220 - Email string, top one from D. Miller to J. Paradise, et al
ETH.MESH.05347751-762 - Email string re Investigator-initiated studied policy
ETH.MESH.05404976 - Commerical-in-confidence Update to the TGA on TVT Secur™ 1 May 2008
ETH.MESH.05406494-497 - Email from Jonathan Meek to Mark Yale Decemeber 17, 2007 RE: TVT Secur* update - POST SCRIPT
ETH.MESH.05446127-139 - Joerg Holste email to Dr. Dieter Engel et al dated 03.13.2006re mesh and tissue contraction in animal (Engleman Trial Exhibit P1846)(Adkins Trial Exhibit P1846)
ETH.MESH.05473737-739 - October 18 <sup>th</sup> 2005 Amendment 2 to Design Validation Study Gynecare TVT* Secur System

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ETH.MESH.05475773-822 - Borist Batke powerpoint - The (clinical) argument of lightweight mesh in abdominal surgery (Engleman Trial Exhibit P1274)(Adkins Trial Exhibit P1274)
ETH.MESH.05475775 - Boris Batke Powerpoint -- showed Eth.mesh.05475775 - court sustained William's objection re foundation (Adkins Trial Exhibit P1274)
ETH.MESH.05479411 - The (clinical) argument of lightweight mesh in abdominal surgery; Ultrapro* Mesh PowerPoint Slide (Adkins Trial Exhibits P1276 (Redacted))
ETH.MESH.05479535 - Chart of Tpes of Mesh and whether they are microporous, medium or macroporous (Adkins Trial Exhibits P1278)
ETH.MESH.05479535 - Mesh porosity chart (Engleman Trial Exhibit P1278)
ETH.MESH.05479535 - Type of meshes by category: microporous, medium, macroporous.
ETH.MESH.05495419 - Shrinking Meshes? (Adkins Trial Exhibits DX22809)
ETH.MESH.05498026-028 - Email from Raimo Sump to Dharini Amin October 17, 2005 RE: TVT SECUR Minutes - Team Meeting October 11th 2005_ Agenda October 18th 2005
ETH.MESH.05529274-75 - Gynecare TVT Tension Free Support for Incontinence
ETH.MESH.05529653 - Email string re - Problem statements for TVT brainstorming meeting
ETH.MESH.05530449-478 - December 10 <sup>th</sup> 2005 Product Design Validation Report Gynecare TVT* Secur System
ETH.MESH.05534022 - Revision History for TVT Secur application FMEA
ETH.MESH.05559108-109 - Email from Gary Borkes to Dan Smith October 25, 2005 RE: TVT-S Des Val Comments (Adkins trial exhibit P1318)
ETH.MESH.05559898-901 - Email from Dan Smith to Gary Borkes November 18, 2005 RE: Design Validation Review Meeting TVT-S
ETH.MESH.05560563-564 - Email from Patricia Hojnoski to Martin Weisberg September 13, 2005 RE: Clinical Expert Report
ETH.MESH.05560579-80 - Email from Patricia Hojnoski to Martin Weisberg September 15, 2005 RE: Clinical Expert Report
ETH.MESH.05572912-913 - Ethicon Professional Education Description
ETH.MESH.05585033-049 - Presentation regarding Ultrapro by Boris Batke (Adkins Trial Exhibits P1324 (Redacted))
ETH.MESH.05588123-126 - Stephen Wohler Email - AW: How inert is polypropylene? July 9, 2007
ETH.MESH.05598522 - Ethicon Gynecare US Commercialization Decision US Discussion Guide for Use with Customers 5/15/2012
ETH.MESH.05600916-923 - Ethicon Inc. Background Information Gynecare Pelvic Floor Repair Prodcuts and Gynecare TVT Secure May 29, 2012 (Engleman Trial Exhibit P1327)
ETH.MESH.05641666-670 - Report: Animal Study/TVTx - 12 weeks Explantation, July 30, 2004 by S. Landgrebe November 4, 2004
ETH.MESH.05644163-171 - Pelvic Floor Repair-Surgeon's Feed-back on Mesh Concept
ETH.MESH.05675500 - Ethicon Gynecare WW Commercialization Decision Chuck Austin message to WW associates 5/29/2012
ETH.MESH.05795097-104 (Adkins trial exhibit P1352)
ETH.MESH.05795537-99 - TVT Professional Education Program: Speaker's Guide.
ETH.MESH.05799233-39 - TVT Exact IFU
ETH.MESH.05916450 - Chronic Pain-Prevention, Future - Bioengineers point of view-D21929 (Powerpoint)
ETH.MESH.05916450 - Macroporous PowerPoint Slide (Adkins Trial Exhibits P1369 (Redacted))

**Production Materials**

ETH.MESH.05918776 - E-mail from Jill Schiaparelli to others regarding Marlex Experience (Adkins Trial Exhibits P1371 (Redacted))
ETH.MESH.05918776 - Email re: Marlex Experience
ETH.MESH.05920616-617 - E-mail from Martin Chomiak to Boris Batke and others regarding Defining light weight mesh (Adkins Trial Exhibits P1373 (Redacted))
ETH.MESH.05958248 - Surgeons Resource Monograph
ETH.MESH.05998805-806 - Piet Hinoul Email RE: ALERTE TVT ABBREVO - Plaintiff's Exhibit 3837
ETH.MESH.05998835-836 - Piet Hinoul Email Re: ALERTE TVT ABBREVO
ETH.MESH.06050437-438 - Email from Aran Maree to Teng Chuan Khoo December 6, 2007 RE: TVT-Secur Investigation update
ETH.MESH.06050487-488 - Email from Aran Maree to Jan Law November 15, 2007 RE: TVT Secur Follow-up
ETH.MESH.06050497-498 - Email from Aran Maree to Jan Law November 13, 2007 RE: TVT Secur Customers 2007 by Month
ETH.MESH.06050509 - Email from Aran Maree to Darryl Harkness November 20, 2007 RE: TVT Secur discussions Somerville Tues 20 Nov
ETH.MESH.06050509- Depo Ex. 3 to the Deposition of Aran Maree taken on 07.23.13 - Email from Aran Maree to Darryl Harkness, et al. re: TVT Secur discussions Somerville Tues 20 Nov. (Adkins Trial Exhibits DX24544)
ETH.MESH.06050795-796 - Memo to TVT Secure DHF #0000120 from Gary Borkes RE: TVT Secur 12 month post launch review August 17, 2007
ETH.MESH.06050830-832 - Email from Jan Law to Aran Maree October 30, 2007 RE: Gynecare TVT SECUR Technical Guide & Updates
ETH.MESH.06050906 - Email from Danielle Hunt to Aran Maree October 31, 2007 RE: TVT-SECUR
ETH.MESH.06050913-919 - Email from Aran Maree to Robert Scherini November 1, 2007 RE: TVT Secur update
ETH.MESH.06051011-1014 - Email from Sateesh Yelisetti to Aran Maree November 2, 2007 RE: URGENT: Meeting with the Australian Regulator to discuss TVT Secur performance.
ETH.MESH.06051023-026 - E-mail from Robert Scherini to others regarding Urgent: Meeting to discuss TVT Secur performance (Adkins Trial Exhibits P1390 (Redacted))
ETH.MESH.06051155-157 - Email from Aran Maree to David Robinson November 13, 2007 RE: Australia update
ETH.MESH.06051320-321 - Depo Ex. 4 to the Deposition of Aran Maree taken on 07.23.13 - Summary of Gynecare TVT Secur System Critical Steps: standardized teaching approach based on August preceptor meeting. (Adkins Trial Exhibits DX24545)
ETH.MESH.06055060 - Letter to Robyn Chu RE: April 2007 Prostheses List - Application to list Gynecare TVT Secur from Robyn Bilston
ETH.MESH.06070148-153 - Email from aran Maree to Ramy Mahmoud June 2, 2009 RE: TVT-S follow up
ETH.MESH.06150472 - Email from David Robinson to Charman Barham November 9, 2007 No Subject
ETH.MESH.06151215-217 - Email from David Robinson to Cheryl Bogardus March 29, 2007 RE: 6 Month Secur Data
ETH.MESH.06151983-84 - David Robinson email to Allison London Brown dated 08.26.2006 re TVT-S results to week 5 (31 patients) (Engleman Trial Exhibit P1403)(Adkins Trial Exhibit P1403)
ETH.MESH.06212717-719 - Email from Jonathan Meek to Mark Yale December 17, 2007 RE: TVT Secur* Update



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ETH.MESH.06382976-987 - Jia, X. Efficacy and safety of using mesh or grafts in surgery for anterior and/or posterior vaginal wall prolapse: systematic review and meta-analysis. BJOG 2008; 115: 1350-1361
ETH.MESH.06403724-740 - 17-page copy of document entitled "3-Month Sheep Study (So04/2-2-1)" (Adkins Trial Exhibit P1411 (T-3126)
ETH.MESH.06479808-885 - Clinical Study Report Study Code 300-05-002 Draft June 2012
ETH.MESH.06592243 - 09.14.2012 Email from Carl Nilsson to Laura Angelini
ETH.MESH.06593827-829 - Letter to Gorsky re: Prolift decommercialization decision
ETH.MESH.06695438 - Justification for Utilizing the Elasticity Test as the Elongation Requirements on TVT LCM
ETH.MESH.06706997-7010 - August 23, 2005 Memo to Dan Smith RE: Final report, PSE Accession Number 05-0395, PROJECT Number 67379
ETH.MESH.06707079-083 - Protocol to Evaluate Effect of reinsertion of TVT SECUR device on its Functionality and Device Integrity in a Human Cadaver Model
ETH.MESH.06717961-992 - September 12, 2005 Memo to Dan Smith RE: Report Amendment 1, PSE Accession Number 05-0396, Project Number 67379
ETH.MESH.06828907-909 - (03.24.2005) Email string, top one from Kimberly Hunsicker to Laura Angelini, et al. re: ICS submission.
ETH.MESH.06860553-558 - Memo RE: Dan's inventive nature and creativity
ETH.MESH.06861281 - Scott Ciarrocca email to David Robinson and Dan Smith dated 01.21.2008 re TVT Secur Data (Engleman Trial Exhibit P1437)
ETH.MESH.06881576-80 - Email string re-TVTO
ETH.MESH.06887138-40 - Waltregny email written on behalf of Professor de Leval re IFU
ETH.MESH.06887241-244 - David Waltregny email 7.16.04 re TVT-O
ETH.MESH.06887244 - 07.16.04 David Waltregny email to Dan Smith re: TVT-O.
ETH.MESH.06887245-246 - Dan Smith Email 7.15.04
ETH.MESH.06893564-565 - Email from Folke Flam to Aviram Suchard dated 09.25.2006 re feedback after using TVT Secur after the launch (Engleman Trial Exhibit P1452)(Adkins Trial Exhibit P1452)
ETH.MESH.06893952 - Evaluation of UltraPro Meshes
ETH.MESH.06894461 - Klinge U, et al. Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model. Journal of Surgical Research 103, 208-214 (2002). (Engleman Trial Exhibit P1454)
ETH.MESH.06917699-704 - Form For Customer Requirements Specification (CRS) For Project TVT-O PA
ETH.MESH.06923868-871 - TVTO-PA Clinical Strategy - 8.21.13 Exhibit A.M. Mitchell T-2177
ETH.MESH.06927231-235 - Email string re-Scion PA commercail recommendation
ETH.MESH.06927248-249 - Dan Smith email to Paul DeCosta et al dated 03.19.2010 re Scion Evaluation Comparison file (Engleman Trial Exhibit P1460)(Adkins Trial Exhibit P1460)
ETH.MESH.07039973-975 - Email from David Robinson to Dan Smith March 22, 2007 RE: TVT World Registry Nilsson
ETH.MESH.07088826-827 - Email from Dhinagar Subramanian to Sheri Dodd January 30, 2008 RE: NICE IP Review - single incision slings.
ETH.MESH.07088877-878 - Email from Judith Gauld to David Robinson May 28, 2008 RE: FW: NICE IP - Single Incision Sub Urethral Slings
ETH.MESH.07090179-181 (Adkins trial exhibit P1463)
ETH.MESH.07104840-841 - Email from Julie Bird to Judi Gauld October 23, 2008 RE: FW: IMPORTANT - Information regarding FDA Publication on the use of Mesh
ETH.MESH.07181042-043 (Adkins trial exhibit P1464)

**Production Materials**

ETH.MESH.07186593-624 (Adkins trial exhibit P1467)
ETH.MESH.07192929 - Investigating Mesh Erosion in Pelvic Floor Repair Powerpoint
ETH.MESH.07201006 - Prolift Professional Education Slide Deck (2007)
ETH.MESH.07201869-884 - Final Report: Ethicon Study No. SO04/2-2-1 A 3-month pre-clinical trial to assess the fixation force of a new TVT (TVTx) in the sheep model
ETH.MESH.07201885-903 - LPT Report No. 19285/05
ETH.MESH.07201904-917 - LPT Report No. 19281/05
ETH.MESH.07201918-939 - LPT Report No. 19283/05
ETH.MESH.07226481 - Ethicon (Burkley) response to Clave paper re degradation
ETH.MESH.07226579-590 - 2000 - TVT CER
ETH.MESH.07318311-313 - de Leval Email Re: TVT ABBREVO ALERT - French and English Email and English Translation Certification - Plaintiff's Exhibit 3613
ETH.MESH.07383730-31 - Email string re-Ultrapro mesh information-identical mesh to Prolift +M
ETH.MESH.07387254-257 - Email RE: August Status Report - Gynecare marketing [11.6.13 Exhibit T-3365]
ETH.MESH.07396541-546 - Procedural Pearls & Frequently Asked Questions
ETH.MESH.07455220 - 3.6.2012 Response to email from C. Huntington RE: inertness of polypropylene mesh
ETH.MESH.07876572-819 - Traditional 510(K) Notification Gynecare TVT Secur* System K052401
ETH.MESH.07876722-723 - Memo to Herbert P. Lerner from Hector H. Herrera September 22, 2005 RE: K052401 Gynecare TVT Secur System
ETH.MESH.07876820-925 - K052401: Response to FDA's Request for Additional Information. Gynecare TVT Secur* System
ETH.MESH.07898852-871 - Linda Nichols email to Linda Answell et al dated 12.01.2004 re TVTx Charter document for 12/06 GAT meeting (Engleman Trial Exhibit P1527) (Adkins Trial Exhibits P1527 (Redacted) (T-2019)
ETH.MESH.08003181-96 - TVT Patient Brochure
ETH.MESH.08003215-230 - Ethicon Copy Review Submission form: GYNECARE TVT Tension-free Support for Incontinence Patient Brochure. Submitted by Robin Osman dated 07.12.2006 (Engleman Trial Exhibit P1536)
ETH.MESH.08003231-46 - TVT Patient Brochure
ETH.MESH.08003263-278 - Ethicon Copy Review Submission form: GYNECARE TVT Tension-free Support for Incontinence Patient Brochure (Including TVT Secur) dated 05.29.2009 (Engleman Trial Exhibit P1539)
ETH.MESH.08003263-278 - TVT Secur IFU
ETH.MESH.08003279-294 - TVT Patient Brochure
ETH.MESH.08003279-294 - TVT Secur IFU
ETH.MESH.08003295-302 - TVT Patient Brochure
ETH.MESH.08041930-931 - Michelle Irvin email RE 12.08.2010 post call notes (Engleman Trial Exhibit P2563)
ETH.MESH.08117473 - Gynecare TVT Exact Profession Education (Updated).
ETH.MESH.08156958 - Gynecare TVT Tension-Free Support for Incontinence: Advanced Users Forum for the Experienced Clinician.
ETH.MESH.08165497-99 - Meeting Minutes-TVT Development Team Meeting
ETH.MESH.08167452-453 - E-mail chain, top one from Laura Angelini to Zenobia Walji regarding R: Prof. Klutke - Confidential (Adkins Trial Exhibits DX20768; P1553)
ETH.MESH.08219141 - Update to the TGA on TVT Secur™ 1 May 2008

**Production Materials**

ETH.MESH.08299913-917 - Nilsson C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. Int Urogynecol J 2013; 24(8): 1265-9 [9.11.13 Exhibit T-1271]
ETH.MESH.08307644-45 - April 5, 2013 Hinoul email and attached study spreadsheets
ETH.MESH.08311158 - Results - 175 Patients Enrolled and Randomized
ETH.MESH.08315779 - Clinical Expert report-09.25.2012
ETH.MESH.08319128-129 - Ethicon DM Sales Rep Do's and Don'ts [7.11.13 Exhibit T 791]
ETH.MESH.08334244-45 - Email string re: Photographs of LCM vs MCM with powerpoint attachment
ETH.MESH.08476210 - Fax from FDA requesting changes to labeling
ETH.MESH.08476217-24 - Fax from FDA requesting changes to labelling
ETH.MESH.08568006-012 - Abstracts Feola 2011 - Abs Stress-shielding: the impact of mesh stiffness on vaginal function (Engleman Trial Exhibit P2564)
ETH.MESH.08568006-12 - Feola A, et al. Stress Shielding-The Impact of Mesh Stiffness on Vaginal Function. Female Pelvic Medicine & Reconstructive Surgery, Vol 17, No 5, Suppl 2, Sept/Oct 2011.
ETH.MESH.09029183-184 - 3 Run Repeatability Study of FSMK0238
ETH.MESH.09100506 - Prolift Professional Education Slide Deck (2005)
ETH.MESH.09238537-541 - Memo to TVT Secure DHF #0000120 from Gary Borkes RE: TVT Secur 12 month post launch review August 17, 2007
ETH.MESH.09264945-46 - Prolene Mesh Re-Design Project
ETH.MESH.09306898-910 - Incontinence - Plaintiffs Exhibit 4164-R
ETH.MESH.09625731-737 -NDA 16-374 4.16.69
ETH.MESH.09629447-448 - Letter to Dr. Grigsby RE: Prolene Polypropylene Suture, U.S.P., NDA #16-374
ETH.MESH.09630649 - 4.26.1973 FDA Letter RE: NDA 16-374
ETH.MESH.09634081 - Section 6 - Info concerning the quantity of drug distributed
ETH.MESH.09634318 - Prolene Package Insert
ETH.MESH.09634664-77 - 1990 FDA reclassification letter
ETH.MESH.09634664-88 - July 5, 1990 FDA Order
ETH.MESH.09656792
ETH.MESH.09656795
ETH.MESH.09744858-63 - TVT Patient Brochure
ETH.MESH.09744866-67 - TVT Abbrevio
ETH.MESH.09746948-998 - License and Supply Agreement [Rosenzweig Exhibit 21 - 12.22.15]
ETH.MESH.09747038-097 - Medscand Agreement
ETH.MESH.09747337-369 - Asset Purchase Agreement
ETH.MESH.09888187-223 - Seven Year Data for Ten Year Prolene Study - Plaintiff's Exhibit 4102
ETH.MESH.09911296-299 - Dan Smith email dated 11.13.2008 re things to consider as we assess next steps for a next generation sling (Engleman Trial Exhibit P1676) (Adkins Trial Exhibit P1676)
ETH.MESH.09922570-578 - R&D Memorandum of PA Mesh Assessments for TVTO-PA Revision 1
ETH.MESH.09951746-747 - Scott Ciarrocca email to Katrin Elbert dated 02.27.2009 re minime discussion at the board meeting (Engleman Trial Exhibit P1677)(Adkins Trial Exhibit P1677)
ETH.MESH.10150872 - Supplier Chart
ETH.MESH.10179518-636 - Clinical Evaluation Report - Gynemesh PS signed by P. Hinoul on 04.26.2013
ETH.MESH.10216874-875 - Email string RE: AUGS lecture-content of discussions
ETH.MESH.10226089-091 - Email from Robert Zipfel to Greg Prine August 28, 2007 RE: FW:
ETH.MESH.10281860 - Clinical Expertise TVT Midurethral sling: market Update Prof Ed Slide Deck

**Production Materials**

ETH.MESH.10575607-13 - Prolene Mesh - Biological Evaluation in Rabbits
ETH.MESH.10982896-909 - LPT Report No. 19282/05
ETH.MESH.11335589-605 - Risk Assessment Summary for the Gynecare TVT SECUR™ System Revision History for 100146510
ETH.MESH.11335728
ETH.MESH.11336474-87 - Ten Year In Vivo Suture Study Scanning Electron Microscopy-5 Year Report
ETH.MESH.11543641 - Powerpoint GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
ETH.MESH.12009027-35 - Gynemesh II-New Mesh Design
ETH.MESH.12831391-393 - September 30, 1987 Letter to Dr. Melveger
ETH.MESH.12831391-404 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH.12831391-92 - P4128 - IR Microscopy of Explanted Prolene received from Prof. R. Guidoin.
ETH.MESH.12831405 - June 15, 1982 Memo to Dr. Melveger RE: Crack Depth in Explanted Prolene, Polypropylene Sutures
ETH.MESH.14020602 - Dr. Gregory Bolton email to Kathy Hampton dated 09.05.2007 re TVT Secur (Engleman Trial Exhibit P1769)
ETH.MESH.14369950 - ISO 14971 - Medical Devices - Application of risk management to medical devices
ETH.MESH.15057318 - Dr. David Robinson memo analysis dated 02.23.2006 re elongation characteristics of laser-cut Prolene mesh for TVT Secur
ETH.MESH.16357664-68 - Therapeutic Products Directorate
ETH.MESH.16416002-004 - Helen Kahlson Email Re: Conversion to Laser Cut TVT
ETH.MESH.17636681-84 - Identification of Issue - Problem Statement-Description
ETH.MESH.17666960-969 - Email from Andrew Meek to nathangoodyear@mac.com July 26, 2007 RE: TVT SECUR Preceptor Meeting 8/24: Somerville, NJ
ETH.MESH.17776990-7011 - Biocompatibility Risk Assessment Report for TVT
ETH.MESH.22138619-628 - Performance Evaluation Report: Corporate Product Characterization
ETH.MESH.22617620-770 - Letter to FDA re K974098 TVT
ETH.MESH.22631022-2029 - TVT - Response to Section 39 Request
ETH.MESH.22634691-92 - Email re - Physician and Patient Labeling Updates to Ethicon Urogynecologic Surgical Mesh - D-8
ETH.MESH.22865906-21 & ETH.MESH.24255174-89 - Email re - Ethicon 510(k) amendments for labeling changes - D-7
ETH.MESH.PM 000067 - TVT- Secur DVD CR 7.12.06
ETH.MESH.PM.000001 - Prolift Professional Education Videos
ETH.MESH.PM.000006 - Anatomy Videos
ETH.MESH.PM.000007 - Prolift Professional Education Videos
ETH.MESH.PM.000009 - Anatomy Videos
ETH.MESH.PM.000014 - Prolift Professional Education Videos
ETH.MESH.PM.000015 - Prolift Professional Education Videos
ETH.MESH.PM.000019 - Prolift Professional Education Videos
ETH.MESH.PM.000027 - Prolift Professional Education Videos
ETH.MESH.PM.000032 - Prolift Professional Education Videos
ETH.MESH.PM.000033 - Prolift Professional Education Videos
ETH.MESH.PM.000034 - Prolift +M Professional Education Videos
ETH.MESH.PM.000037 - Prolift Professional Education Videos

**Production Materials**

ETH.MESH.PM.000038 - Prolift Professional Education Videos
ETH.MESH.PM.000039 - Prolift Professional Education Videos
ETH.MESH.PM.000048 - Prolift +M Professional Education Videos
ETH.MESH.PM.000057 - Anatomy Videos
ETH.MESH.PM.000058 - Prolift Professional Education Videos
ETH.MESH.PM.000065 - Prolift Professional Education Videos
ETH.MESH.PM.000068 - Anatomy Videos
ETH.MESH.PM.000075 - Prolift Professional Education Videos
ETH.MESH.PM.000076 - Prolift Professional Education Videos
ETH.MESH.PM.000078 - Prolift Professional Education Videos
ETH.MESH.PM.000088 - Anatomy Videos
ETH.MESH.PM.000089 - Anatomy Videos
ETH.MESH.PM.000090 - Anatomy Videos
ETH.MESH.PM.000092 - Prolift +M Professional Education Videos
ETH.MESH.PM.000134 - Anatomy Videos
ETH.MESH.PM.000145 - Prolift +M Professional Education Videos
ETH.MESH.PM.000151 - Anatomy Videos
ETH.MESH.PM.000154 - Anatomy Videos
ETH.MESH.PM.000179 - TVT SECUR Key Tech Points 5.24.2007 Color Original from Prof Ed DVD
ETH.MESH.PM.000179 - TVT Secur_IFU_V5e_2005 to disc_Original from Prof Ed DVD
ETH.MESH.PM.000190 - Prolift Professional Education Videos
ETH.MESH.PM.000192 - Prolift Professional Education Videos
ETH.MESH01816988-990
ETH.MESH02017152 - Ethicon Expert Meeting-Meshes for the Pelvic Floor Repair
ETH.MESH-08476311 - Cytotoxicity assessment of Ulstem sling
ETH-02386 - Cosson, M. Prospective Clinical Assessment of the Total Vaginal Mesh (TVM) Technique for Treatment of Pelvic Organ Prolapse - 6 and 12 month results
ETH-02387 - Lucente, V. Prospective clinical assessment of the total vaginal mesh (TVM) Technique for treatment of pelvic organ prolapse - 6 and 12 month results.
ETH-02388 - Amblard, J., et al. From the TVM to the Prolift (Gynecare): evolution of a technique for prosthetic support to treat prolapse via the vaginal route, concerning a retrospective multicentric series of 794 patients (684 TVM/110 Prolift). (2007)
ETH-02653 - Fatton, B., et al. Preliminary results of the "Prolift" technique in the treatment of pelvic organ prolapse by vaginal approach: a multicentric retrospective series of 110 patients. IUGA (2006) [Abstract 275].
ETH-02750-755 - Hinoul P. A Prospective Study to Evaluate the Anatomic and Functional Outcome of a Transobturator Mesh Kit (Prolift Anterior) for Symptomatic Cystocele Repair. Journal of Minimally Invasive Gynecology (2008) 15, 615-620
ETH-03084 - Murphy, M., et al. Early U.S. experience with vaginal extraperitoneal Colpopexy using a polypropylene graft (Prolift TM) for the treatment of pelvic organ prolapse. Int Urogynecol J (2006) 17(S2):S273 [Abstract 392].
ETH-03220-221 - Cosson, M., et al. Preservation of uterus when treating prolapse by Prolift TM does not significantly reduce risk of early post surgical complications and failures. [Abstract 89].
ETH-03223 - Dedet, B. Transvaginal repair of genital prolapse by the Prolift technique: outcome one year after surgery.
ETH-03568-578 - (03.01.2005) Summary Memo for Revision B of the Gynecare Prolift Design Failure Modes Effects Analysis (dFMEA).

**Production Materials**

ETH-07153-158 - Gynecare Prolift Clinical Expert Report signed by Charlotte Owens on 01.14.05.
ETH-07247-303 - (03.02.2005) Approvals and Summary Memo for Version A of the Gynecare Prolift Application Failure Modes Effects Analysis (aFMEA).
ETH-18393-408 - Presentation: Gynemesh PS by Paul Parisi 10.04.2002.
ETH-37788-793 - Gynecare Prolift Clinical Expert report
ETH-49659-660 - Email from A. Kirkemo to H. Gadot, et al. re: RAB- TPro redefinition
ETH-59475-508 - (5.16.2008) Ethicon Prolift Physician IDI's.
ETH-60188-195 - Hiltunen R. Low-Weight Polypropylene Mesh for Anterior Vaginal Wall Prolapse - A Randomized Controlled Trial. Obstet Gynecol 2007;110-455-62
ETH-80303 - (02.02.2006) Email string, top one from Michel Cosson to Scott Ciarrocca re: Prolift package insert.
Ethicon Sponsored Device Use Training History
Excerpts from Budke trial transcript (Day 4, 01.08.2015).
February 20, 2008 email from Andrew Beveridge -- "increased tape stiffness -- my feeling it is due to the laser cutting" (Adkins Trial Exhibit P1102)
February 27, 2009 email from Jason Hernandez attaching PPT titled "TVT World Registry" (Adkins Trial Exhibit P0086)
February 27, 2009 email from Scott Ciarrocca -- includes the "Watch Out" slide (Adkins Trial Exhibit P1677)
French TVM Study - Mesh Exposure Rates.
French TVM Study - Primary Endpoint: 20% or greater prolapse recurrence rate = failure of Primary Endpoint.
Guidoin R and Chakfe N. Aneurysmal Deterioration of Arterial Substitutes.
Gynecare Gynemesh PS IFU (English Only) LAB-0012266 Rev: 3, released 02.03.15.
Gynecare Prolift - Product Devise Design Safety Assessment (DDSA)
Gynecare TVT Secur No Bigger than your Palm. No Less than a revolution brochure.
GYNECARE TVT SECUR* Preceptors Meeting Paris - 13/11/2006 Menahem Neuman, MS Israel
Gynecare TVT SECUR* System Procedural Steps Guideline
Gynecare TVT™ Family of Products Chart
Gynecology Solutions
Gynemesh PS Approval File (FDA) Requested August 15, 2007 Folder: K013718 - 131 pages; Summary: Product: GYNEMESH PROLENE SOFT (POLYPROPYLENE) NON ABSORBABLE SYNTHETIC SURGICAL
Gynemesh PS Study - Mesh exposure/Prolapse recurrence
Gynemesh PS: Rectocele repair literature/study review
Harel Gadot Powerpoint re "Incontinence Platform" - showed "TVT Secur YTD Findings" (Adkins Trial Exhibit P0784)
Heniford DVD Transcription
Hinoul study (Adkins Trial Exhibit DX30603)
History of Secur PowerPoint - Alison London-Brown P-1384 (Adkins Trial Exhibits DX24643R)
HMESH_ETH_11642462 - Franchise Regulatory Labeling Guidance - Summary of Changes
Incontinence Platform WW Marketing Team Update August 19 <sup>th</sup> Harel Gadot
J&J Credo (Engleman Trial Exhibit P1962)
January 29, 2009 email from Meng Chen - "Pardon me....." (Adkins Trial Exhibit P1139)
JEB Engineering Design Limited - FMEA Potential Failure, Mode and effects analysis (Process FMEA)
Johnson & Johnson - Our Credo [8.9.13 A.M. Mitchell Exhibit T-3134]



**Production Materials**

Johnson & Johnson Credo (Adkins Trial Exhibit P2131 (Redacted) (T-3134)
June 20, 2006 email from Harel Gadot -- "Worries about us launching Secur without any clinical data" (Adkins Trial Exhibit P0953)
June, 2009 Klosterhalfen intermediate report on explanted mesh (highlighted)
Kaufman MR. Contemporary role of autologous fascial bladder neck slings: a urology perspective. Controversies in Female Pelvic Reconstruction, 2012, 39(3): 317-323.
Klinge Presentation PVDF: a new alternative? Meeting o Hernia Experts Exhibit P-1944
KOL Interview of Carl Nilsson -- "will not use laser cut" (Adkins Trial Exhibit P1128)
Letter to Editor re: Ostergard & Sternschuss 2012 Post-implantation alterations of polypropylene in the human.
Librojo updated TVT Declaration (10-23-15) [12 pages]
March 19, 2010 email from Dan Smith -- "TVT Secur considered a failure and did not warrant line extension" (Adkins Trial Exhibit P1460)
Marketing Powerpoint from 2006 titled TVT-Secur; William objected; court sustained objection -- unclear what will happen now (Adkins Trial Exhibit P0842 (Possibly P0482)
McCabe email re - Sheath Sales Tool - 464
Memo to S. Ciarrocca re: Regulatory Strategy - Project D'Art; Rev 3
Miller JM, et al. Clinical Evaluation of Monofilament Polypropylene Suture. Am. Surgeon 33 - 666-70. (1967)
MSDS-Marlex Polypropylenes
November 12, 2007 email from David Robinson - "IFU is fundamentally misleading" (Adkins Trial Exhibit P0290)
November 26, 2002 email from Axel Arnaud (Adkins Trial Exhibit P0933)
November 5, 2007 email from Catherine Beath -- Frazier fails in 13 cases (Adkins Trial Exhibit P0286)
Our Credo[8.9.13 A.M. Mitchell Exhibit T-3134
P4117 - Figure 7: Sample 13159, Lot #3405405 (Photograph)
P4118 - Figure 26: J8041-13675 (Photograph)
P4122 - SEM Figure 183: Sample J7959 13409 (Photographs)
Patient Injury Due to Mesh Inflammation and Contraction
Payments to Medscand [9.16.13 Exhibit T-3192]
Payments to Medscand by J&J [9.16.13 Exhibit T-3183]
Payments to Ulmsten as Consultant [9.16.13 Exhibit T-3204]
Pelvic Floor Repair Platform (05.15.2006).
Powerpoint -- "Brand Equity Statement" dated January 2010 -- "cardinal sin" (Adkins Trial Exhibit P1008)
Powerpoint -- "Gynemesh PS is lighterweight larger pore" (Adkins Trial Exhibit P0292)
Powerpoint - GYNECARE GYNEMESH* PS Nonabsorbable PROLENE* Soft Mesh Awareness Module
Powerpoint - LCM Project: Photographs Comparing Laser Cut Mesh vs. Mechanical Cut Mesh
Powerpoint - Prospective Clinical Assessment of TVM - 1 Year Results
Powerpoint Slide: Studies Show Prolift is Safe and Effective.
Powerpoint: Factors related to mesh shrinkage: What do we know? A review of literature and internal studies (02.23.2007).
Powerpoint: Mesh Shrinkage: How to assess, how to prevent, how to manage?
Powerpoint: Pores Collapse Under Tension
Powerpoint: Prolift Unsafe/Defective Mesh Design
Powerpoint: R&D Perspective - The Journey from Prolift to Prolift +M.

**Production Materials**

Powerpoint: Stand & Deliver Pelvic Floor Repair
Presentation: Graft or No Graft by A. Arnaud.
Presentation: Review of Surgical Techniques Using Mesh by David Robinson
Prolene Resin Manufacturing Specifications 1.23.03 [DX23600-R.1-3]
Prolift +M IFU
Prolift Surgical Technique Guide
Published clinical data and RCTs - Ethicon.com - 4204-C
Schumpelick - Hernia Repair Sequelae (Engleman Trial Exhibit P1918)
September 25, 2006 email from Harol Gadot -- "defectes that have to be attended to" and "FYI - do not distribute" (Adkins Trial Exhibit P1452)
Seven Year Dog Study - T-2263
Summary of Payments to Experts Lucente to Williams
T-2262 - Deposition Subject Matter Thomas Barbolt Deposition 1.8.14
T-919 - Communication to Surgeons Regarding the Gynecare TVT Secur System (Adkins Trial Exhibits DX24558)
Te Linde's Operative Gynecology - Plaintiff's Exhibit 3958
Thunder: Technical Review, Somerville (02.28.2008)
T-Pro (Thunder) Pipeline Leadership Team (PLT)
T-Pro (Thunder) Pipeline Leadership Team (PLT) Stage Gate: Discovery Initiation (08.25.2008).
Treatment of SUI with TVT-S (Production 36_000162_2435031_d)
TVM 6 Month Data Review
TVT Abbrevio IFU - 01.2015
TVT Adverse Reactions (Adkins Trial Exhibit P2377 (T-1640)
TVT Adverse Reactions (risks allegedly known by Ethicon medical directors prior to TVT Secur launch) dated 12/12/2015 (Engleman Trial Exhibit P2377)
TVT Exact IFU - 01.2015
TVT IFU - 01.2015
TVT Patient Brochure - 2015
TVT Secur Powerpoint to Quality Board (Adkins Trial Exhibit P0706)
TVT-O la bandelette trans-obturatrice (Photograph)
TVT-Obturator - 01.2015
TVT-Obturator IFU - 01.2015
TVT-SECUR Australian Experience Discussion with TGA Canberra, 9 January 2008
TVT-Secur Photograph (Adkins Trial Exhibit P2130 (T-3127)
TVT-Urinary Adverse Reactions (Adkins Trial Exhibit P2378 (P-1641)
US TVM Study - Mesh Exposure Rates.
US TVM Study - Primary Endpoint: 20% or greater prolapse recurrence rate = failure of Primary Endpoint.

**Company Witness Depositions**

<b>Deponent [Date of Deposition]</b>
Angelini, Laura - 09.16.2013 Deposition Testimony
Angelini, Laura - 09.17.2013 Deposition Testimony
Angelini, Laura - 11.06.2013 Deposition Testimony
Angelini, Laura - 11.14.2013 Deposition Testimony
Arnaud, Axel - 07.19.13 Deposition Testimony
Arnaud, Axel - 09.25.13 Deposition Testimony
Arnaud, Axel - 11.15.2012 Deposition Testimony
Arnaud, Axel - 11.16.2012 Deposition Testimony
Barbolt, Thomas - 01.08.2014 Deposition Testimony
Barbolt, Thomas - 10.09.2012 Deposition Testimony
Beath, Catherine - 07.11.13 Deposition Testimony
Chen, Meng - 10.29.2013 Deposition Testimony
Chen, Meng - 10.30.2013 Deposition Testimony
Ciarrocca, Scott - 03.29.2012 Deposition Testimony
Ciarrocca, Scott - 03.30.2012 Deposition Testimony
Hart, James - 09.17.2013 Deposition Testimony
Hart, James - 09.18.2013 Deposition Testimony
Hart, James - 12.20.2013 Deposition Testimony
Hart, James - 12.30.2013 Deposition Testimony
Hellhammer, Brigitte - 09.11.2013 Deposition Testimony
Hellhammer, Brigitte - 09.12.2013 Deposition Testimony
Hinoul, Piet - 01.13.2014 Deposition Testimony
Hinoul, Piet - 01.14.2014 Deposition Testimony
Hinoul, Piet - 01.15.2014 Deposition Testimony
Hinoul, Piet - 02.01.16 Carlino Testimony Played in Court
Hinoul, Piet - 04.05.2012 Deposition Testimony
Hinoul, Piet - 04.06.2012 Deposition Testimony
Hinoul, Piet - 06.26.2013 Deposition Testimony
Hinoul, Piet - 06.27.2013 Deposition Testimony
Hinoul, Piet - 09.18.2012 Deposition Testimony
Hinoul, Piet - 09.19.2012 Deposition Testimony
Holste, Joerg - 07.29.2013 Deposition Testimony
Holste, Joerg - 07.30.2013 Deposition Testimony
Holste, Joerg - 12.14.2012 Deposition Testimony
Holste, Joerg - 12.15.2012 Deposition Testimony
Hunischer, Kimberly - 01.01.2014 Deposition Testimony
Hunischer, Kimberly - 04.01.2014 Deposition Testimony
Isenberg, Richard - 11.05.13 Deposition Testimony
Isenberg, Richard - 11.06.13 Deposition Testimony
Jones, Scott - 01.25.2012 Deposition Testimony
Jones, Scott - 11.15.2011 Deposition Testimony
Jones, Scott - 11.16.2011 Deposition Testimony
Kammerer, Gene - 10.17.2012 Deposition Testimony
Kammerer, Gene - 12.03.2013 Deposition Testimony
Kammerer, Gene - 12.05.2013 Deposition Testimony
Kirkemo, Aaron - 01.06.14 Deposition Testimony

**Company Witness Depositions**

Kirkemo, Aaron - 01.07.14 Deposition Testimony
Klinge, Uwe - 11.04.2015 Deposition Testimony
Klinge, Uwe - 11.10.2014 Deposition Testimony
Klosterhalfen, Bernd - 02.02.2014 Deposition Testimony
Lamont, Daniel - 09.11.2013 Deposition Testimony
Lisa, Bryan - 12.19.2011 Deposition Testimony
Lisa, Bryan - 12.20.2011 Deposition Testimony
Lucente, Vincent - 06.10.2014 Deposition Testimony
Lucente, Vincent - 11.02.2012 Deposition Testimony
McCoy, Sheri - 04.22.2010 Deposition Testimony
McCoy, Sheri - 10.12.2012 Deposition Testimony
Nager, Charles - 01.14.2016 Deposition Testimony
Nager, Charles - 06.10.2014 Deposition Testimony
O'Bryan, Sean - 05.18.2012 Deposition Testimony
Owens, Charlotte - 06.19.13 Deposition Testimony
Owens, Charlotte - 06.20.13 Deposition Testimony
Owens, Charlotte - 09.12.2012 Deposition Testimony
Owens, Charlotte - 09.13.2012 Deposition Testimony
Parisi, Paul - 01.24.2012 Deposition Testimony
Parisi, Paul - 02.06.2013 Deposition Testimony
Parisi, Paul - 06.05.2013 Deposition Testimony
Parisi, Paul - 06.06.2013 Deposition Testimony
Parisi, Paul - 12.13.2011 Deposition Testimony
Parisi, Paul - 12.14.2011 Deposition Testimony
Robinson, David - 03.13.2012 Deposition Testimony
Robinson, David - 03.14.2012 Deposition Testimony
Robinson, David - 07.24.2013 Deposition Testimony
Robinson, David - 07.25.2013 Deposition Testimony
Robinson, David - 08.23.2012 Deposition Testimony
Robinson, David - 09.11.2013 Deposition Testimony
Rosenzweig, Bruce - 01.14.2016 Deposition Testimony
Rosenzweig, Bruce - 12.22.2015 Deposition Testimony
Rovner, Eric - 01.14.2016 Deposition Testimony
Rovner, Eric - 08.26.2014 Deposition Testimony
Selman, Renee - 06.21.2013 Deposition Testimony
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